

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO WAVE 1 / TVT-O CASES	Master File No. 2:12-MD-02327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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RULE 26 EXPERT REPORT OF DR. ABBAS SHOBEIRI

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure. All of the opinions that I offer in this Report I hold to reasonable degree of medical or scientific certainty.

I. QUALIFICATIONS

Currently, I am Professor of Obstetrics and Gynecology, Virginia Commonwealth University School of Medicine & George Washington University Professor, Cell Biology & Anatomy, Graduate College, OUHSC, and Vice Chair, Gynecologic Subspecialties, Inova Fairfax Hospital Women's Center. Previously, I was Professor and Section Chief of Female Pelvic Medicine & Reconstructive Surgery and a Professor of Cell Biology and Anatomy at the University of Oklahoma Health Sciences Center.

I was recruited to the University of Oklahoma Health Sciences Center in 2002 as the first fellowship trained physician in Female Pelvic Medicine and Reconstructive Surgery in Oklahoma. Prior to settling in Oklahoma, I obtained my Bachelor degree from the University of Washington in Seattle, Medical Degree from Tufts University in Boston,

and completed my residency and fellowship at Tulane and Louisiana State University in New Orleans. My CV is attached as Exhibit A.

I established the OU Pelvic and Bladder Health Center which now encompasses an ACGME accredited 3 year fellowship program, an International Continence Society and International Urogynecology Association host site for research scholar program, Pelvic Floor Investigation Group (PFIG), OU Basic Science Pelvic Floor Laboratory, and OU International Ultrasound workshop. I have been the recipient of research and educational awards. I have been a grant reviewer for the American College of Obstetrics and Gynecology, the American Urogynecologic Society, and American Federation for Aging Research. I am also a manuscript reviewer for Urology, Journal of Urogynecology & Pelvic Floor Dysfunction, American Journal of Obstetrics and Gynecology, Neurourology & Urodynamics, and Journal of Pelvic Medicine and Surgery. I have authored numerous articles in scientific journals as well as several chapters for textbooks standard to the field of Urogynecology. I am the editor of the textbook entitled: Practical Pelvic Floor Ultrasonography.

I have chaired ultrasound workshops at the International Continence Society, International Urogynecology Association, and multiple institutions around the world. Additionally, I have served on the Research and the Program committees at the American Urogynecologic Society.

My clinical interests include vaginal agenesis and structural abnormalities. My research interests include basic science neuroanatomy and the study of pelvic floor injury using 3D sonography. These include the evaluation and treatment of mesh-related complications.

II. BACKGROUND

The opinions expressed on this report are based on the peer-reviewed medical literature, as well as my experience as an academic urogynecologist with a busy clinical practice. As a urogynecologist and specialist in ultrasound visualization of the pelvic floor, I receive referrals from around the country for mesh-related complications. Patients with mesh-related complications are commonly referred to a tertiary care center for evaluation and treatment because the expertise for repair of these problems requires advanced training. In my current role, I am involved in patient care, teaching, and research.

In addition to my clinical practice treating pelvic organ prolapse and stress urinary incontinence and managing surgical complications, I have special expertise in the imaging of mesh with ultrasound technology. I am recognized as one of the world's experts and have published widely in this area. This expertise provides me with a unique opportunity to visualize the behavior of mesh in vivo and correlate those findings with patient symptoms.

Numerous materials, biologic and synthetic, have been used to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Three-dimensional ultrasound has been shown to be the most effective technique to image these implantable materials. X-ray, CT scan, MRI are not capable of visualizing mesh effectively, however 3D ultrasound rays bounce off the mesh material and make the mesh easily visible.

I, along with some other world experts popularized a technique for the optimal visualization and pelvic floor imaging of pelvic floor structures, including meshes and implants. The procedure used to obtain these images is similar to the traditional endovaginal sonogram, but the way the images are obtained is completely different. The

traditional endovaginal transducer found in most gynecological imaging is an end-fire transducer. The 3D volumes obtained with a BK side-fire transducer allow for optimal imaging of the vaginal wall, urethra, and anal canal. All images are obtained with a BK Medical 8838 high resolution, 6-12 MHz, 360° rotational transducer. The 8838 has a 65mm X 5.5mm acoustic footprint and penetration depth of up to 85mm. This transducer is similar in size and shape to the traditional end-fire transducer used in gynecological imaging. Pressing the 3D acquisition button moves the internal probe crystals to obtain images every 0.5 degrees for 360 degrees. The images are packaged into a 3D volume that can be manipulated in any plane. The 3D ultrasound imaging takes 30 seconds and minimizes patient discomfort. 2D Ultrasonography is typically extremely operator dependent. 3D imaging allows for an automated acquisition. This reduces operator dependence; the data set is stored and can later be manipulated and analyzed. This methodology has been published and is now widely accepted by the medical community.

I am familiar with the Ethicon prolapse and SUI polypropylene mesh products specifically, in addition to my knowledge relating to mesh products generally. I have personally managed patients with complications related to these devices and have removed TVT-O devices from patients referred to me. I initially used Ethicon's TVT-O but abandoned it because of the high rates of pain complications that I saw in my practice and became apparent in the peer-reviewed medical literature. I have also evaluated patients from other physicians with the same pathology. A patient suffering from groin pain subsequent to TVT-O surgery may not be respond to mesh removal. Managing mesh complications and performing mesh removal surgeries occupy a significant amount of my

professional time. I have removed a significant number of mesh and TVT-O devices since its introduction in 2003, primarily for pain and erosion.

III. SUMMARY OF OPINIONS

1. Mesh complications are unlike those seen with other pelvic surgery in terms of onset, frequency, severity, character, and responsiveness to treatment.
2. Three-dimensional endovaginal ultrasound (EVUS) is a reliable, reproducible, and well-accepted method for assessing pelvic floor conditions, including mesh complications.
3. Mesh complications, including those resulting from transobturator slings, are associated with distinct findings on EVUS.
4. Mesh findings on EVUS include deformation (flat, folding, prominence or convoluted, etc.), shrinkage and contraction, and residual mesh.
5. Mesh contraction (defined by IUGA/ICS as shrinkage or reduction in size) is a well-known occurrence, can be detected by EVUS, and has clinical consequences.
6. The lateral portions of the Gynecare TVT-O of mesh devices are difficult, if not impossible to remove, even with the aid of advanced imaging and surgical skill, and result in significant morbidity for patients.
7. The Gynecare TVT-O is associated with an unacceptably high rate of chronic pain.
8. EVUS evaluation combined with physical examination provides objective evidence of the mechanism and cause of mesh-related symptoms.
9. In a woman presenting with groin pain and/or vaginal/mesh pain and sexual pain following insertion of the TVT-O device, a device-related condition is, more likely than not, the most likely diagnosis on the list of differential diagnoses.
10. In a woman presenting with groin pain and/or vaginal/mesh pain and sexual pain following placement of the TVT-O device, these symptoms are, more likely than not, associated with the material and placement flaws of the TVT-O described in this report.
11. The surgical management of mesh complications requires advanced training and specialized expertise.
12. Timely recognition and referral of mesh complications is of utmost importance to prevent prolonged suffering of patients.

13. Most patients with mesh complications are referred for treatment by someone other than the implanting doctor. This indicates that complications are under-appreciated by community doctors and often results in a delay of appropriate treatment.
14. The TVT-O is defectively designed as described in the body of this report.
15. Ethicon did not adequately warn physicians and patients about known complications and risks associated with its TVT-O device.
16. There are safer alternatives to the TVT-O that have equivalent or superior efficacy.
17. Because of the rate and severity of complications and the lack of improved efficacy over other surgical procedures to treat SUI, the risks of the TVT-O outweigh its benefits and should not be used

IV. TVT-O METHOD OF INSERTION

The Gynecare TVT Obturator (“TVT-O”) is an inside-out transobturator sling, the first and only device to be inserted in this fashion. It consists of a ½ X 18 inches strip of PROLENE polypropylene mesh covered by a plastic sheath. PROLENE is an older higher weight, smaller pore mesh designed for abdominal wall hernia repairs. The product description (see Instructions for Use below) states that *when used as a suture*, it has been reported to be non-reactive and to retain its strength indefinitely in clinical use. However, the IFU does not address its reactivity or strength when placed transvaginally in the transobturator space. I saw no evidence that this was tested by Ethicon. Testing of a device in the target space is critical to demonstrate safety - different parts of the body react differently to foreign materials.

The TVT-O is inserted blindly through the following anatomical structures: vaginal epithelium, pubocervical fascia, obturator internus muscle, obturator membrane, obturator externus muscle, adductor magnus muscle, adductor brevis muscle, and gracilis muscle insertion before it exits through the skin. This space contains dense nerves and blood vessels. Additionally, gynecologists and urologist had no familiarity with the anatomy in

this region; there is no other pelvic reconstructive surgery for prolapse or SUI that uses this space other than those using mesh. This represented a radical departure from SUI procedures that utilize the retropubic space.

Ethicon's Instructions for Use (below) describe the procedure. The insertion requires special instruments and is not an easy operation to perform. The trajectory required for placement makes it difficult for surgeons to know where it is being placed and allows a small margin of error. In addition, the anatomy varies from one individual to the next making a one-size-fits-all device unreliable in this space. The TVT-O is inserted through the pubocervical fascia, obturator internus muscle, obturator membrane, obturator externus muscle, adductor magnus muscle, adductor brevis muscle, and gracilis muscle before exiting the skin. Through its course, it passes through or in close proximity to nerves and blood vessels of varying size. Prior to the introduction of transobturator slings and armed trocar-based prolapse mesh "kits", gynecologic surgeons had never operated in this space.

GYNECARE TVT *Obturator* Atraumatic Winged Guide, Sterile Single Use

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

Important:

This package insert is designed to provide instructions for use of the GYNECARE TVT* *Obturator* System, including the GYNECARE TVT *Obturator* device, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT *Obturator* device. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION

The GYNECARE TVT *Obturator* System is a sterile, single patient use procedure kit consisting of:

GYNECARE TVT *Obturator* device

The GYNECARE TVT *Obturator* device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phthalocyanine blue, Color Index Number 74160) PROLENE* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and that providing elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT Helical Passers

The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT *Obturator* device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT *Obturator* device. The Helical Passer MUST not be bent or deformed in any way.

GYNECARE TVT Atraumatic Winged Guide

The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

INDICATIONS

The GYNECARE TVT *Obturator* device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

INSTRUCTIONS FOR USE

(Note: hand positions shown in illustrations may vary)

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. Optionally, the labia may be sutured laterally to provide exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.
5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. (See Figure 1)

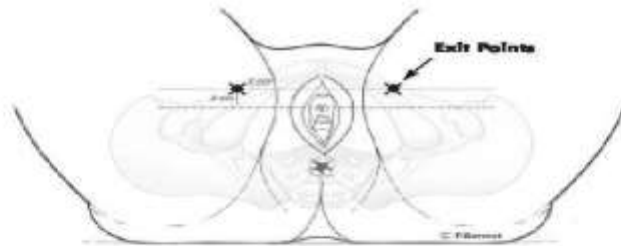


FIG. 1

6. Using Allis clamps for traction, make a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus.

(Note: It is suggested that the device insertion be completed on one side before beginning dissection of the second side.)

Using a "push-spread technique", begin blunt dissection preferably using pointed, curved scissors. The path of the lateral dissection should be oriented at a 45° angle from the midline, with the scissors oriented either on the horizontal plane or with the tips pointed slightly upward (See Figure 2). Continue dissection toward the "junction" between the body of the pubic bone and the inferior pubic ramus. (See Figure 2)

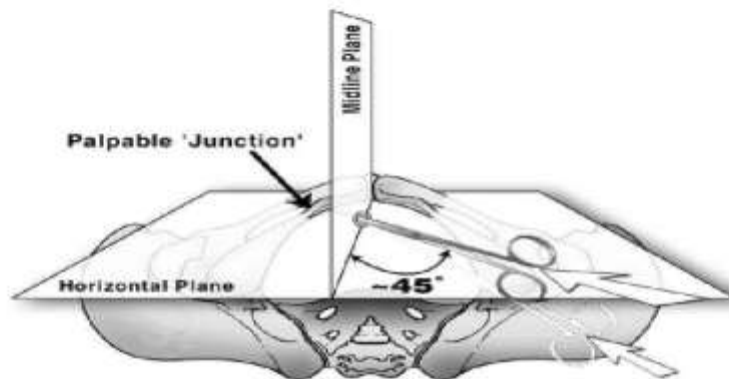


FIG. 2

When the "junction" between the body of the pubic bone and the inferior pubic ramus is reached, perforate the obturator membrane. A loss of resistance can be felt when the membrane is perforated. The channel should be approximately 5–7 mm in diameter and no deeper than 5 cm. Dissection beyond 5 cm may allow unintended entry into the Space of Retzius. If the bone is not reached after dissecting 5 cm, re-evaluate that the angle of dissection is correct.

7. Remove the GYNECARE TVT Winged Guide from the package. (See Figure 3)

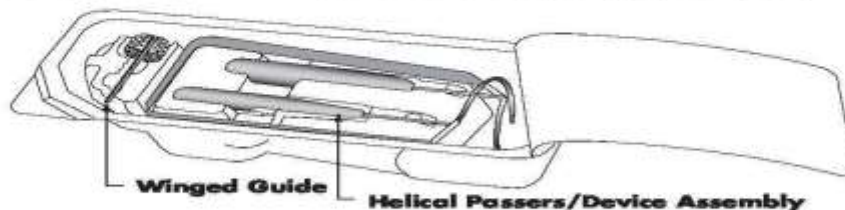


FIG. 3

8. Insert the GYNECARE TVT Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. Loss of resistance can be felt as the Winged Guide passes through the obturator membrane.

If difficulty is encountered during insertion of the guide, reconfirm the direction of the tract with the scissors.

(Note: The open side of the guide must be facing the surgeon. The bendable tab can be bent to increase the length of the guide if needed, See Figure 5.)

9. Remove the GYNECARE TVT Helical Passers/Device Assembly and the GYNECARE TVT Obturator device assembly from the sterile pack (See Figure 3 for components).

(Note: To ensure correct orientation of the Helical Passers and tape, verify that the GYNECARE logo and thumb indent on the plastic handle are facing the surgeon, and that the points are on the outside facing the surgeon. The Helical Passer in the surgeon's left hand must be used on the patient's right side; See Figure 4.)

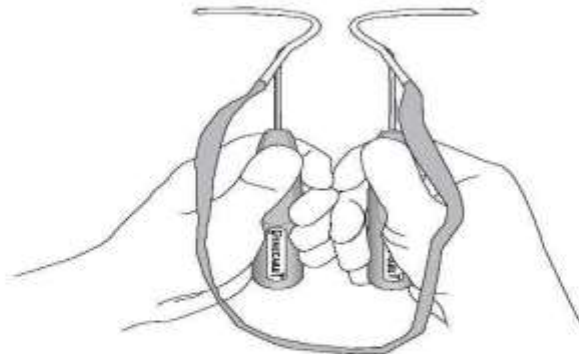


FIG. 4

10. Place one of the Helical Passers on the sterile drape or other suitable sterile location until needed. Assure that the tape is not twisted.
11. Insert the correct GYNECARE TVT Helical Passer into the dissected tract following the channel of the GYNECARE TVT Winged Guide. Push the device inward, traversing, and slightly passing the obturator membrane. Make sure the device handle is oriented so the straight tip of the Helical Passer is aligned with the channel in the GYNECARE TVT Winged Guide and remains in that orientation until the tip traverses the obturator membrane. (See Figure 5)

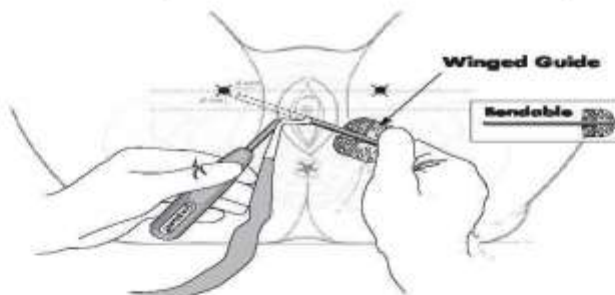


FIG. 5

12. Once in this position, remove the GYNECARE TVT Winged Guide and keep sterile for later use on the same patient.

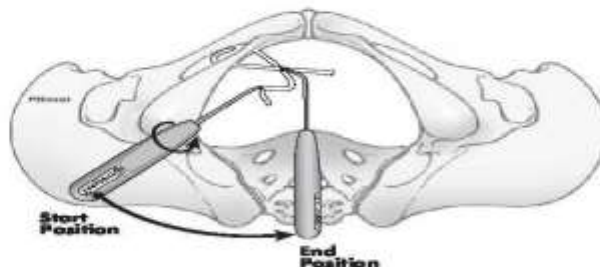


FIG. 6

13. Once the GYNECARE TVT Winged Guide has been removed, rotate the handle of the Helical Passer simultaneously as you move the handle towards the midline. (See Figure 6) **(Note: Never allow the handle to be orientated in a horizontal position.)**

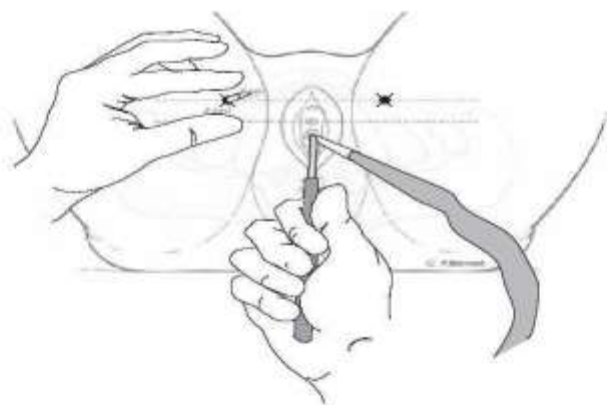


FIG. 7

14. The point of the Helical Passer should exit near the previously determined exit points (See Figure 7). However, slight skin manipulation may be required. If the skin incision has not been previously made, make it at the point where the tip of the helical passer tents the skin. When the tip of the plastic tube appears at the skin opening, grasp it with a clamp and, while stabilizing the tube near the urethra remove the Helical Passer by a reverse rotation of the handle. (See Figure 8)

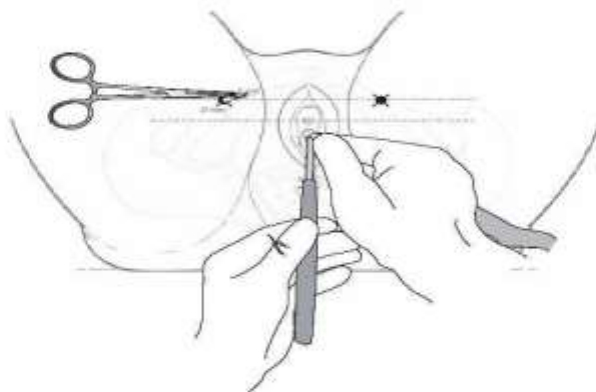


FIG. 8

15. Pull the plastic tube completely through the skin until the tape appears. (See Figure 9)

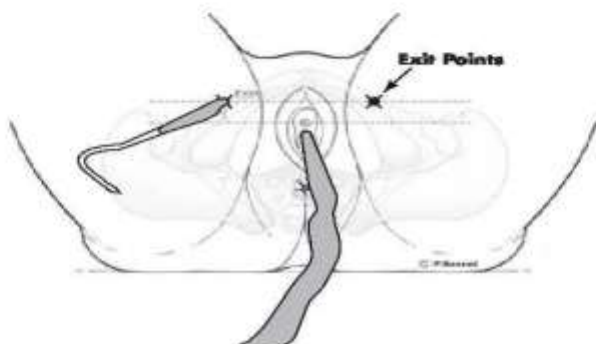


FIG. 9

16. Repeat the technique on the patient's other side ensuring that the tape lies flat under the urethra. (See Figure 10)

(Note: If a twist in the tape is discovered, ensure that the twist is not positioned under the urethra after the excess tape is pulled through.)

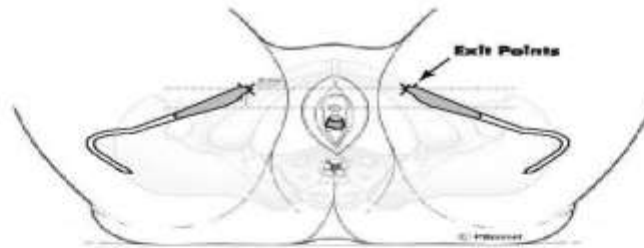


FIG. 10

17. When both plastic tubes have been extracted through the skin incisions, cut the plastic tubes from the tape and plastic sheaths. Position the tape loosely e.g. without tension, and flat under the mid-urethra. At this stage a cough test can be performed. This allows adjustment of the tape so that only a few drops of urine are lost during the cough. (See Figure 11)

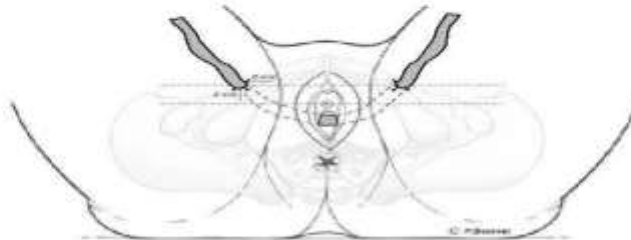


FIG. 11

When the tape is in position, remove the plastic sheath that covers the tapes. To avoid positioning the tape with tension, place a blunt instrument (e.g., scissors or forceps) between the urethra and the tape during removal of the plastic sheaths.

(Note: Premature removal of the sheath may make subsequent adjustments difficult.)

18. Following tape adjustment close the vaginal incision. Cut the tape ends at the exit points just below the skin of the inner thigh. Close the skin incisions with suture or surgical skin adhesive.
19. Cystoscopy can be performed at the discretion of the surgeon. If cystoscopy was performed following the first passage, make sure the bladder is emptied prior to initiating passage of the second side. Post-operative indwelling catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2–3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT *Obturator* procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT *Obturator* procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT *Obturator* procedure before employing the GYNECARE TVT *Obturator* device.
- Acceptable surgical practice should be followed for the GYNECARE TVT *Obturator* procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT *Obturator* procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the mid-urethra.
- Do not perform this procedure if you think the surgical site may be infected or contaminated.

- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, in case of pregnancy delivery via cesarean section should be considered.
- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT *Obturator* System. To minimize this risk, make sure to place the tape as described above.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT *Obturator* device or its components. Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

HOW SUPPLIED

The GYNECARE TVT *Obturator* System is provided sterile (ethylene oxide) for single use. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

STORAGE

Recommended storage conditions for the GYNECARE TVT *Obturator* System single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

V. DISCUSSION

When one looks at the older urogynecology textbooks, the complications of surgical procedures were mostly limited to postoperative medical complications such as postoperative bleeding, pulmonary embolus, myocardial infarctions, and deep venous thrombosis. With the introduction of synthetic materials and mesh kits into vaginal reconstructive surgery over the past decade, unprecedented and unexpected complications have occurred. These are often difficult to manage and require innovative solutions.¹

The placement of mesh increased rapidly in POP and stress urinary incontinence surgery; however, many complications occurred due to inappropriate techniques dictated by the devices, and many complications were recognized too late and were poorly managed. Ironically, in an effort to avoid bladder injuries associated with retropubic slings which were reversible, manufacturers resorted to a transobturator approach which came with its own set of complications which were not reversible. Many of these techniques, including the Gynecare TVT-O, placed mesh through muscles and densely innervated areas where gynecologic surgeons were not accustomed to operating. Complications unique to mesh (vaginal mesh extrusion, urinary tract erosion, mesh contraction, and chronic pain conditions) have been reported with increasing frequency.² Some of these complications are new and unique and require innovative surgeries that may or may not correct the problem. Symptoms of suspected vaginal mesh complications include vaginal discharge and/or bleeding, dyspareunia, pelvic pain, and recurrent urinary tract infections.

¹ Giulio Santoro, MD, Pawel Wiczorek, MD, and S. A. Shobeiri, MD. *Endovaginal Three Dimensional Sonography*. Pelvic Floor Disorders 2010.

² Abed, H., et al. (2011). "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review." *Int Urogynecol J* 22(7): 789-798; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." *Neurourol Urodyn*.

The most common complications associated with mesh procedures, in our experience and as reported in the medical literature, are pain, dyspareunia, erosion, and de novo urinary tract symptoms.³ These complications are very different from those seen in native tissue pelvic surgery in terms of onset, frequency, severity, character, and responsiveness to treatment. Vaginal mesh exposure, contraction and other complications can be serious and are associated with substantial morbidity. They may result in pelvic/vaginal pain on movement and dyspareunia. In addition, delay in diagnosis can cause chronic problems, which are difficult to treat even after the removal of the mesh. Ultrasound has shown exceptional sensitivity and specificity over physical examination for detection of vaginal mesh.⁴ Persistent pain after mesh implantation is a serious matter. It is more likely than not the consequence of nerve entrapment or damage, mesh contraction, and scarring. Surgical intervention is often required to alleviate symptoms. It basically

³ Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." *Female Pelvic Med Reconstr Surg* 20(3): 126-130; Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study." *Am J Obstet Gynecol* 210(2): 163 e161-168; Hammett, J., et al. (2014). "Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery." *Int Urogynecol J* 25(4): 465-470; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." *Neurourol Urodyn.*; FDA Safety Communication. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Silver Spring, MD: Food and Drug Administration (US), Center for Devices and Radiological Health. Available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>; Haylen, B. T., et al. (2011). "An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery." *Neurourol Urodyn* 30(1): 2-12; Lee, D., et al. (2014). "Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes." *Expert Rev Med Devices*: 1-16; Rogo-Gupta, L. and S. Raz Pain Complications of Mesh Surgery. *Complications of Female Incontinence and Pelvic Reconstructive Surgery*. H. B. Goldman: 87-105; Brubaker, L. and B. Shull (2012). "A perfect storm." *Int Urogynecol J* 23(1): 3-4.

⁴ Manonai, J., G. Rostaminia, L. Denson, and S. A. Shobeiri. "Clinical and Ultrasonographic Study of Patients Presenting with Transvaginal Mesh Complications." *Neurourol Urodyn* (Jan 25 2015).

involves mobilization of the mesh, division of the fixation arms, and excision of contracted mesh. Apart from possible irreversible damage to the nerve in the case of nerve injury, secondary vaginismus and pelvic floor muscle spasm may occur. Secondary vaginismus is caused by the woman's fear of the pain and is quite difficult to treat.⁵

Many groups have published widely on the evaluation and management of mesh complications resulting from SUI and prolapse procedures. In 2012, our group reported on 133 patients who presented to our clinic for complications of vaginal mesh. The median number of complications per patient was three. The most commonly reported complication was exposure of mesh into the vagina (63.1%). Other complications included: pain (42.8%), infected mesh (6%), dyspareunia (38.3%), vaginal bleeding (24.8%), vaginal discharge (27%), stress urinary incontinence recurrence (29.3%), and pelvic organ prolapse recurrence (25.5%). Some patients had multiple complications. From this study, we determined that the majority (79%) of the patients presenting to our facility were referred by a physician other than the original vaginal mesh surgeon. In our study, the majority of patients with complications secondary to implantation of vaginal mesh who underwent reoperation at tertiary care centers were referrals and had the original implantation performed elsewhere.⁶

We recently reported a clinical and ultrasonographic study of patients presenting with transvaginal mesh complications which included 79 patients. Of these, 51.9% had

⁵ Marcus-Braun, N. and P. von Theobald (2010). "Mesh removal following transvaginal mesh placement: a case series of 104 operations." Int Urogynecol J 21(4): 423-430; von Theobald P. Place of mesh in vaginal surgery, including its removal and revision. Best Pract Res Clin Obstet Gynaecol 2011; 25:197-203; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

⁶ Rostaminia, G., et al. (2012). "Referral pattern for vaginal mesh and graft complications to the University of Oklahoma Pelvic and Bladder Health Clinic." J Okla State Med Assoc 105(9): 356-358.

vaginal/pelvic pain and 82.2% of sexually active patients had dyspareunia. In this study, we determined that endovaginal ultrasound (EVUS) was helpful in the diagnosis and management of mesh complications.⁷ In an abstract submitted for presentation at the 2016 American Urogynecologic Society we have shown that there is simply no rhyme or reason for the course of transobturator slings. Ultrasound shows that there seem to be no way to reliably place them were prescribed.

Multiple publications have determined that three-dimensional endovaginal ultrasound (EVUS) is a reliable, reproducible, and well-accepted method for assessing pelvic floor conditions, including mesh complications. Mesh complications are associated with distinct findings on EVUS.⁸ MRI and X-ray imaging have been found to be inferior in their ability to visualize graft materials when compared with ultrasound because they

⁷ Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." *Neurourol Urodyn*.

⁸ e.g. Shobeiri A *Practical Floor Ultrasonography* Springer 2014; Santoro G, Wieczorek A, Shobeiri S, Mueller E, Pilat J, Stankiewicz A, et al. Interobserver and interdisciplinary reproducibility of 3D endovaginal ultrasound assessment of pelvic floor anatomy. *Int Urogynecol J*. 2010;22:53–9; Santoro GA, Wieczorek AP, Dietz HP, Mellgren A, Sultan AH, Shobeiri SA, et al. State of the art: an integrated approach to pelvic floor ultrasonography. *Ultrasound Obstet Gynecol*. 2011;37:381–96; Santoro GA, Wieczorek AP, Stankiewicz A, Wozniak MM, Bogusiewicz M, Rechberger T. High-resolution three-dimensional endovaginal ultrasonography in the assessment of pelvic floor anatomy: a preliminary study. *Int Urogynecol J Pelvic Floor Dysfunct*. 2009;20(10):1213–22. PubMed PMID: 19533007. [English]; Chantarasorn V, Shek KL, Dietz HP. Sonographic appearance of transobturator slings: implications for function and dysfunction. *Int Urogynecol J*. 2011; 22:493–8; Santoro GA, Wieczorek AP, Shobeiri SA, Mueller ER, Pilat J, Stankiewicz A, et al. Interobserver and interdisciplinary reproducibility of 3D endovaginal ultrasound assessment of pelvic floor anatomy. *Int Urogynecol J Pelvic Floor Dysfunct*. 2011;22:53–9; Santoro GA, Wieczorek AP, Shobeiri SA, Stankiewicz A. Endovaginal ultrasonography: methodology and normal pelvic floor anatomy. In: Santoro GA, Wieczorek AP, Bartram CI, editors. *Pelvic floor disorders: imaging and multidisciplinary approach to management*. Dordrecht: Springer; 2010. p. 61–78; Santoro GA, Wieczorek AP, Bartram C. *Pelvic floor disorders: imaging and multidisciplinary approach to management*. 1st ed. Italia: Springer; 2010. p. 729; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." *Neurourol Urodyn*.

may visualize swelling and edema associated with mesh but not the mesh itself.⁹ Three-dimensional endovaginal ultrasound is a useful tool to evaluate outcomes of surgery with implants, delineate the reason for complications or failure, and plan treatment, especially in patients with a complicated treatment history.¹⁰

EVUS can be used to determine the location of a mesh device, as well as its deformability and movement with Valsalva. These findings correlate with surgical outcomes.¹¹ In another abstract submitted for publication at 2016 American Urogynecologic Society meeting, we describe various mesh patterns associated with pain and extrusion. Multicompartment imaging is useful in determining the location and function of synthetic implants.¹² It can help clarify the symptoms of pain and erosion associated with mesh implants. It is also useful in patients with a history of mesh surgery in whom the exact nature of the surgery or the site of mesh placement is unknown. Imaging can be performed preoperatively to understand the intrapelvic course of the mesh implant in order to plan mesh revision surgery better. It can also be performed following mesh removal surgery to determine if there is any mesh left behind.¹³ Common mesh findings on EVUS include deformation (flatness, folding, prominence or convoluted, etc.), shrinkage and contraction, fragmentation, migration, and residual mesh.

The most common complication following placement of the TVT-O is pain. The mechanisms leading to pain after TVT-O is multifactorial. A combination of nerve or muscle damage/entrapment and/or tension on vaginal or perivaginal structures as a result

⁹ Hegde, A. and Davila, G. W.. Endovaginal Imaging of Vaginal Implants. S. A. Shobeiri: 133-152.

¹⁰ *Id.* at 134.

¹¹ *Id.* at 139.

¹² *Id.* at 144.

¹³ *Id.*

of retraction and scarring are probable explanations. These are findings regularly confirmed on ultrasound and histological examination. For example, Feiner and Maher defined a series of ‘mesh contraction’ in 17 women surgically managed with mesh excision. All subjects presented with intractable pelvic pain, dyspareunia and tenderness on pelvic examination associated with vaginal scarring.¹⁴ Velemir reported a series of Prolift implants, correlating severe mesh retraction seen ultrasonographically with anterior wall prolapse recurrence.¹⁵ The lateral arms of the TVT-O tape function very much like the arms of a prolapse repair kit.

I reviewed Ethicon documents confirming that Ethicon knew that the TVT-O was associated with more pain than other slings. These included the “confidential” meeting held with prof. de Leval and Ethicon executives just months after the introduction of the product. Concerns about pain complications also provided the main impetus for the development of the TVT Abbrevio. Reported complaints to Ethicon also clearly demonstrated patient and doctor concerns.¹⁶

Mesh contraction is reported extensively in the medical literature.¹⁷ The FDA, in its 2011 PHN states “*Mesh contraction (shrinkage) is a previously unidentified risk of*

¹⁴ Feiner, B. and C. Maher (2010). "Vaginal mesh contraction: definition, clinical presentation, and management." Obstet Gynecol 115(2 Pt 1): 325-330.

¹⁵ Velemir, L., et al. (2008). "Urethral erosion after suburethral synthetic slings: risk factors, diagnosis, and functional outcome after surgical management." Int Urogynecol J Pelvic Floor Dysfunct 19(7): 999-1006.

¹⁶ ETH.MESH.03803462; ETH.MESH.03364532; ETH.MESH.02180759; ETH.MESH.00632022; ETH.MESH.03928235.

¹⁷ Dietz, H. P. E., M.; Shek, K. L. (2011). "Mesh contraction: myth or reality?" Am J Obstet Gynecol 204(2): 173 e171-174; Klinge, U., Klosterhalfen, B., Muller, M., Ottinger, A. P., & Schumpelick, V. (1998). "Shrinking of polypropylene mesh in vivo: an experimental study in dogs." The European Journal of Surgery 164(12): 965-969; Deffieux, X., et al. (2007). "Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study." Int Urogynecol J Pelvic Floor Dysfunct 18(1): 73-79; Klosterhalfen, B., et al. (2005). "The lightweight and large porous mesh concept for hernia repair." Expert Rev Med Devices 2(1): 103-117; Gonzalez R., F. K., McClusky D 3rd, Ritter E.M., Lederman, A.,

transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the Oct. 20, 2008 *FDA Public Health Notification*.¹⁸ Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain.” The ICS/IUGA Joint Terminology and Classification of the Complications Related Directly to the Insertion of Prostheses (Meshes, Implants, Tapes) and Grafts in Female Pelvic Floor Surgery lists mesh contraction and defines it as “shrinkage or reduction in size.”¹⁹ “Prominence” is defined as “parts that protrude beyond the surface (e.g. due to wrinkling or folding with no epithelial

Dillehay D. (2005). "Relationship between tissue ingrowth and mesh contraction." World J Surg 29: 1038-1043; Garcia-Urena, M. A., et al. (2007). "Differences in polypropylene shrinkage depending on mesh position in an experimental study." Am J Surg 193(4): 538-542; Gauruder-Burmester, A., et al. (2007). "Follow-up after polypropylene mesh repair of anterior and posterior compartments in patients with recurrent prolapse." Int Urogynecol J Pelvic Floor Dysfunct 18(9): 1059-1064; Tunn, R., et al. (2007). "Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele." Ultrasound Obstet Gynecol 29(4): 449-452; Margulies, R. U., et al. (2008). "Complications requiring reoperation following vaginal mesh kit procedures for prolapse." Am J Obstet Gynecol 199(6): 678 e671-674; Feiner, B. and C. Maher (2010). "Vaginal mesh contraction: definition, clinical presentation, and management." Obstet Gynecol 115(2 Pt 1): 325-330; Velemir, L., et al. (2008). "Urethral erosion after suburethral synthetic slings: risk factors, diagnosis, and functional outcome after surgical management." Int Urogynecol J Pelvic Floor Dysfunct 19(7): 999-1006; Mamy, L., et al. (2011). "Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection." Int Urogynecol J 22(1): 47-52; Letouzey, V., Mousty, E., Huberlant, S., Pouget, O., Mares, P., de Tayrac, R. "Ultrasonographic Scan Evaluation of Synthetic Mesh Used for Vaginal Cystocele Repair Comparing Four Arms Trans Obturator Techniques to Anterior Bilateral Sacro Spinous Ligament and Arcus Tendinous Suspension." J Minim Invasive Gynecol 17(6): S7-S8; Lefranc, O., Bayon, Y., Montanari, S., et al. (2011) Reinforcement Materials in Soft Tissue Repair: Key Parameters

Controlling Tolerance and Performance-Current and Future Trends in Mesh Development. In: Von Theobald, P., et al., Eds., *New Techniques in Genital Prolapse Surgery*, Springer Verlag London Ltd., London.

¹⁸ FDA Safety Communication. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Silver Spring, MD: Food and Drug Administration (US), Center for Devices and Radiological Health. Available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>.

¹⁹ Haylen, B. T., et al. (2011). "An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery." Neurourol Urodyn 30(1): 2-12.

separation).²⁰ Although there is one article in the medical literature by Dietz that questions the evidence for mesh contraction, the methodology in this publication is seriously flawed and does not represent generally held opinions.²¹

There are symptoms and conditions that are unique to mesh. For example, exposure and erosion are only seen with synthetic mesh devices. There are also pain syndromes that are unique to mesh. These are often associated with characteristic findings on ultrasound and pelvic examination. When a patient presents with vaginal pain and sexual pain following a mesh procedure, this condition, more likely than not, is caused by mesh and, more likely than not, is mediated by one or more of the mechanisms discussed in this report. The reason is that mesh produces a unique constellation of symptoms that are characteristic of the presence of mesh and virtually not seen in any other setting. Although a differential diagnosis requires looking at all possible explanations for a given constellation of symptoms, there are very few, if any, other medical conditions that produce the same symptoms as mesh – especially when considered in aggregate.²²

²⁰ *Id.*

²¹ Dietz, H. P. E., M.; Shek, K. L. (2011). "Mesh contraction: myth or reality?" Am J Obstet Gynecol 204(2): 173 e171-174.

²² FDA Safety Communication. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Silver Spring, MD: Food and Drug Administration (US), Center for Devices and Radiological Health. Available at <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>; Rogo-Gupta, L. and S. Raz Pain Complications of Mesh Surgery. Complications of Female Incontinence and Pelvic Reconstructive Surgery. H. B. Goldman: 87-105; Lee, D., et al. (2014). "Meshology: a fast-growing field involving mesh and/or tape removal procedures and their outcomes." Expert Rev Med Devices: 1-16; Novara, G., et al. (2010). "Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence." Eur Urol 58(2): 218-238; Bako, A. and R. Dhar (2009). "Review of synthetic mesh-related complications in pelvic floor reconstructive surgery." Int Urogynecol J Pelvic Floor Dysfunct 20(1): 103-111; Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." Female Pelvic Med Reconstr Surg 20(3): 126-130; Dunn, G. E., et al. (2014). "Changed women: the long-term impact of vaginal mesh complications." Female Pelvic Med Reconstr Surg 20(3): 131-136; Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive

Timely recognition and referral of mesh complications is of utmost importance to prevent prolonged suffering of patients. Unfortunately, doctors in the community are often not aware of the risks of mesh. Complications are underreported. Although mesh insertion seems like an easy procedure, the treatment of complications is challenging and surgical management may require specialized expertise. Even in the best of hands, many patients will continue to have symptoms after removal of mesh. Pain is the most difficult condition to treat effectively. Transobturator slings like TVT-O and the arms of prolapse mesh kits (Prolift) are particularly problematic and difficult, if not impossible, to remove in their entirety.²³

From a clinical perspective, the TVT-O is defectively designed. Features of the TVT-O rendering the product defective include the following:

1. The properties of polypropylene mesh when placed in the transobturator space with the TVT-O device, including chronic inflammation, foreign body reaction, shrinkage/contraction, fibrosis/scarring, hardening, deformation, nerve entrapment, and degradation.
2. The blind passage of synthetic mesh arms through muscle and densely-innervated tissue, resulting in tissue damage and trauma.
3. The high, asymmetrical, and unpredictable degree of shrinkage/contraction of the device including the arms.

surgery: a multicenter study." Am J Obstet Gynecol 210(2): 163 e161-168; Hammett, J., et al. (2014). "Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery." Int Urogynecol J 25(4): 465-470; Manonai, J., et al. (2015). "Clinical and ultrasonographic study of patients presenting with transvaginal mesh complications." Neurourol Urodyn.

²³ Abbott, S., et al. (2014). "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study." Am J Obstet Gynecol 210(2): 163 e161-168; Danford, J. M., et al. (2015). "Postoperative pain outcomes after transvaginal mesh revision." Int Urogynecol J 26(1): 65-69; Hansen, B. L., et al. (2014). "Long-term follow-up of treatment for synthetic mesh complications." Female Pelvic Med Reconstr Surg 20(3): 126-130. Hammett, J., et al. (2014). "Short-term surgical outcomes and characteristics of patients with mesh complications from pelvic organ prolapse and stress urinary incontinence surgery." Int Urogynecol J 25(4): 465-470.

4. The failure of the central portion of the mesh device to lie flat when there is tension from the arms, resulting in curling, roping, and coiling.
5. The difficulty or impossibility of removing the entire device when complications warrant.
6. The need for multiple surgeries to remove mesh.
7. The chance of persistent symptoms, especially pain, even after the device has been removed.
8. The products can result in late onset of complications that may occur indefinitely into the future.
9. The products cause chronic pain syndromes (resulting from nerve entrapment, scarring, mesh deformation and contraction and inflammation), that are often extremely difficult to treat

I have reviewed and am familiar with the Instructions for the Gynecare TVT-O. I have also reviewed the IFUs for many other medical products throughout my career. To make an informed decision of whether or not to use a particular product, the physician must be warned not only of the potential adverse events that may be associated with the product, but also the frequency, severity, duration and potential permanence of those adverse events. In addition, doctors need this information to adequately inform their patients of the risks and benefits of a given treatment option.

The TVT-O IFU lists the following “ADVERSE REACTIONS”:²⁴

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.

²⁴ ETH.MESH.02340829; ETH.MESH.00860239; ETH.MESH.02340974; ETH.MESH.02340756; ETH.MESH.02340902.

- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

In every instance, the reaction listed minimizes the actual risk. “Transient” instead of “permanent”. “Potentiate an existing infection instead of “cause”. “Punctures of lacerations of nerves” at insertion and “may require surgical repair” instead of chronic nerve trauma and neuropathic pain. Tension only due to “over correction” instead of tension resulting from shrinkage and contraction over time.

The “adverse reactions” listed in the IFU are inadequate to inform doctors and patients of the true risks associated with the TVT-O. Severity, frequency, permanence, and responsiveness to treatment are not addressed. I have personally observed and treated patients who have been implanted with a TVT-O who have experienced the following device-related complications, often severe and life-altering (also reported in the peer-reviewed literature):²⁵

²⁵ Hansen, B., et al., *Long-Term Follow-up of Treatment for Synthetic Mesh Complications*, Female Pelvic Med & Reconstr Surg 2014, 20:126-130; Barski D, et al., *Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair*. Surg Technol Int. 2014, 24:217-24.; Shah, et. al., *Mesh complications in female pelvic floor repair surgery and their management: A systematic review*. Indian J Urol. 2012 Apr; 28(2):129-53; Feiner, B., et al., *Vaginal Mesh Contraction: Definition, Clinical Presentation and Management*, Obstet Gynecol 2010, 115:325-330; Morrisoe, S., et al., *The use of mesh in vaginal prolapse repair: do the benefits justify the risks?* Current Opinion in

- Chronic pain syndromes;
- Chronic inflammation of tissue surrounding mesh;
- Excessive scar plate formation, scar banding, and contracture of mesh arms, resulting in asymmetrical pulling on the central portion, causing pain;
- Erosion of mesh into the bladder and recurrent exposure of mesh in the vagina;
- Pudendal neuralgia and other neuropathies;
- Pelvic floor muscle spasm;
- Nerve damage or nerve entrapment pain as a result of mesh scarification and fibrotic bridging;
- Dyspareunia and sexual impairment;
- Deformed, curled, roped, degraded and fragmented mesh upon removal and visualized with ultrasound;
- Encapsulation of mesh (mesh covered in thick scar);
- Vaginal shortening, tightening, stenosis and/or other deformation;
- Infection as a result of the mesh, including bladder infections, vaginal infections, chronic urinary tract infections, and abscesses;
- Recurrent and persistent vaginal erosion and extrusion and visceral erosion;
- De novo urinary symptoms;
- “Hispareunia”.

Under ACTIONS, the IFU states that “animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues which is transient and

Urology 2010, 20:275-279; Blandon, et al., *Complications from vaginally placed mesh in pelvic reconstructive surgery*, Int Urogynecol J 2009, 20:523-31; Jacquetin, B, *Complications of Vaginal Mesh: Our Experience*, Int Urogyn J, 2009, 20:893-6; Margulies et al, *Complications requiring reoperation following vaginal mesh kit procedures for prolapse*, Am J Obstet Gynecol December 2008; Blaivas, J. G., R. S. Purohit, M. S. Benedon, G. Mekel, M. Stern, M. Billah, K. Olugbade, R. Bendavid, and V. Iakovlev. "Safety Considerations for Synthetic Sling Surgery." Nat Rev Urol 12, no. 9 (Sep 2015): 481-509.

is followed by the deposition of a thin layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.” These statements are misleading and inaccurate based on the information known to Ethicon from internal documents and the peer-reviewed scientific literature.²⁶ This information is critical for doctors to know and understand in order to advise their patients of the risks of the permanently implanted device.

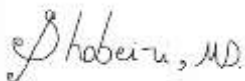
There are safer alternatives than the TVT-O that are at least as effective. Adoption of one or more of these alternatives would have reduced or avoided the foreseeable risks of harm that the TVT-O posed. Failure to utilize one or more of these alternatives rendered the devices not reasonably safe and caused or substantially contributed to the complications and injuries discussed in this report.

Based upon my education, training, experience and knowledge, and my familiarity with the published literature relating to this subject, it is my professional opinion to a

²⁶ e.g. Klinge, U., Klosterhalfen, B., Muller, M., Ottinger, A. P., & Schumpelick, V. "Shrinking of Polypropylene Mesh in Vivo: An Experimental Study in Dogs." *The European Journal of Surgery* 164, no. 12 (1998): 965-69; Klosterhalfen B, Linge U, Rosch R, Junge K. "Long-Term Inertness of Meshes." In *Meshes: Benefits and Risks*. Germany: Schumpelick V, Nyhus L, 2003; Costello, C. R., S. L. Bachman, B. J. Ramshaw, and S. A. Grant. "Materials Characterization of Explanted Polypropylene Hernia Meshes." *J Biomed Mater Res B Appl Biomater* 83, no. 1 (Oct 2007): 44-9; Clave, A., H. Yahi, J. C. Hammou, S. Montanari, P. Gounon, and H. Clave. "Polypropylene as a Reinforcement in Pelvic Surgery Is Not Inert: Comparative Analysis of 100 Explants." *Int Urogynecol J* 21, no. 3 (Mar 2010): 261-70; Iakovlev V., Mekel G., Blaivas J. "Pathological Findings of Transvaginal Polypropylene Slings Explanted for Late Complications: Mesh Is Not Inert [Abstract]." *International Continence Society Meeting Annual Meeting* (2014); Blaivas, J. G., R. S. Purohit, M. S. Benedon, G. Mekel, M. Stern, M. Billah, K. Olugbade, R. Bendavid, and V. Iakovlev. "Safety Considerations for Synthetic Sling Surgery." *Nat Rev Urol* 12, no. 9 (Sep 2015): 481-509. Smith, T. M., S. C. Smith, J. O. Delancey, D. E. Fenner, M. O. Schimpf, M. H. Roh, and D. M. Morgan. "Pathologic Evaluation of Explanted Vaginal Mesh: Interdisciplinary Experience from a Referral Center." *Female Pelvic Med Reconstr Surg* 19, no. 4 (Jul-Aug 2013): 238-41.

reasonable degree of medical certainty that the injuries and complications that I have personally observed, diagnosed and treated associated with the TVT-O are directly attributable to the defective design of these products as described previously. Because of the unique complications, especially chronic pain, associated with the TVT-O, the difficulty removing when problems arise, and the availability of safer alternatives, it is my opinion that the risks of the TVT-O outweigh the benefits. This is why I, and many of my colleagues in academic centers, no longer use TVT-O in practice. However, I continue to see complications from these devices placed by community doctors. As we have reported, some community doctors, who frequently rely on information from medical device companies, may lack an appreciation of the nature and severity of mesh-induced complications. We have shown that patients who have had mesh complications typically don't follow-up with the physician who performed the initial surgery. As such the physicians may remain unaware of the number or the extent of complications arising from their TVT-O procedures.

Dated: February 1, 2016



S. Abbas Shobeiri, M.D.

LITERATURE RELIED UPON

Attached as **Exhibit B**.

FEE SCHEDULE

Dr. Shobeiri's standard rate is \$750/hr; for expert witness testimony \$6,000/day plus travel and lodging expenses.

LIST OF PREVIOUS TESTIMONY

Craft v. Boston Scientific Corp., Case No. 2:12-cv-05898
Nava v. Boston Scientific Corp., Case No. 2:13-cv-14455
Acosta v. C.R. Bard, Inc. Case No. 2:13-cv-06855
Callen, et al. v. C.R. Bard, Inc. Case No. 2:14-cv-14375
Jay, et al., v. C.R. Bard, Inc. Case No. 2:13-cv-08536
Lewis, et al., v. C.R. Bard, Inc. Case No. 2:14-cv-00475
Merrill v. C.R. Bard, Inc. Case No. 2:13-cv-01856
Rueda, et al., v. C.R. Bard, Inc. Case No. 2:13-cv-02175
Sloan, et al., v. C.R. Bard, Inc. Case No. 2:13-cv-22500
Orozco v. Boston Scientific Corp., Case No. MICV2012-03068
McCabe v. American Medical Systems, Inc., Case No. N11C-10-264

Exhibit A

Curriculum Vitae

S. Abbas Shobeiri, M.D., FACOG, FACS, CMPE



Vice Chair, Gynecologic subspecialties
Inova Fairfax Hospital
Professor of Obstetrics & Gynecology^*
Adjunct Professor of Cell Biology*
The University of Oklahoma Health Sciences Center*
George Washington University^
Virginia Commonwealth University^

www.linkedin.com/pub/s-abbas-shobeiri/3/274/99a/en

Curriculum Vitae

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EDUCATION AND TRAINING:

Board Certification	Female Pelvic Medicine and Reconstructive Surgery, FACOG	2013-
	Obstetrics and Gynecology	2003
Professional Certification: Certified Medical Practice Executive		2014
	CUCOG (The Council of University Chairs of Obstetrics and Gynecology) leadership development program	2015-17
Fellowship	Female Pelvic Medicine and Reconstructive Surgery Fellowship Louisiana State University Health Sciences Center New Orleans, LA	1999-2002
Residency	Obstetrics and Gynecology Louisiana State University Health Sciences Center New Orleans, Louisiana	1995-1999
Internship	Internal Medicine Tulane University New Orleans, Louisiana	1994-1995
Graduate School	Executive Healthcare Master of Business Administration Brandeis University Boston, Massachusetts	2016-2017
Medical School	Doctor of Medicine Tufts University School of Medicine Boston, Massachusetts	1990-1994
Undergraduate	Bachelor of Science in Biology University of Washington and Seattle CC Seattle, Washington	1985-1990
	Japanese Language and Literature Aoyama Academy Tokyo, Japan	1982-1985

Curriculum Vitae

i. SERVICE

I. Academic:

2015 -- Vice Chair Gynecological subspecialties, Inova Fairfax Hospital
 2014 – Professor, Obstetrics and Gynecology, VCU, GWU
 2014 -- Professor, Cell Biology, OUHSC
 2002 – 2013 Assistant and subsequently Associate Professor and
 Chief, Section of Female Pelvic Medicine & Reconstructive Surgery/Urogynecology,
 Oklahoma's first fellowship-trained physician in FPMRS, The University of Oklahoma Health
 Sciences Center, Department of Obstetrics & Gynecology

As the division director, I established a new division with a 12 year development plan to sequentially mature three programs:

1- Clinical Services

My role at Inova is to provide and coordinate gynecologic programs at the Inova Fairfax Hospital and across the system to serve our patient population. 2015-

Inova academic compensation subcommittee 2015-
 Inova competency committee 2015-

Prior to joining Inova, I spent 13 years establishing “**OU Women's Pelvic & Bladder Health Center**” starting at 2002. Since then, this entity has grown to include seven multidisciplinary clinics that bring together the expertise of the best specialists in Oklahoma.

Clinic awards:

- Excel Awards: 2008, 2009, 2010, 2011 (Not given 2012-14), 2015
- 2010 National Health care week 10-17 to 10-23 1st place-
Tracking/Testing UTI's
- 2011 National Health care week 10-16 to 10-22 2nd place- Press
Ganey-Information about delays
- 2008 National Health care week 10-19 to 10-25 1st place-Tracking
and Treating UTI's

“**Women's Surgical Units**” at the OU Medical Center to deliver women a more personalized surgical care.

“**The Pelvic Floor Laboratory**” at the OU Physicians. This clinical laboratory offers the state of the art testing and we believe it is the best in the nation.

“**Oklahoma Pelvic Floor Network (OKPFN)**” as an educational resource to rural physicians and physical therapists.

“**OU Health Care for Executive Women**” a specialized pay for service program for busy executive leaders in Oklahoma.

2- Clinical and Basic Science Research

- My role at Inova is to coordinate gynecologic research programs at the Inova Fairfax Hospital and across the system to serve our patient population.

Prior to joining Inova, I spent 13 years establishing “**The Pelvic Floor Research Laboratory**” at the OUHSC. Secured dedicated research space that is used for pelvic floor studies. We have become known nationally for our readiness to perform clinical trials. We have dedicated research nurses at the Women's Health Center to achieve this end.

Curriculum Vitae

- I have collaborated extensively with various basic scientists around OUHSC campus, in particular with Pharmacology department to investigate the pathophysiology of muscle degeneration in pelvic floor disorders.
- I created the “**OU Pelvic Medicine Fund**” to be used for resident and fellow’s unfunded research.

3- Educational Programs for Medical Students, Residents, and Fellows

- I am a Professor of Cell Biology and Anatomy due to my expertise in pelvic floor Anatomy. Initially, in addition to being involved with the problem based learning courses, I proctored medical students during abdominal and pelvic dissection. Between 2007-15, I have also given the clinical correlation lecture in Pelvic floor anatomy to the first year medical students.
- I created a suturing and knot tying module that I have handed off to a junior faculty.
- I have established educational programs for Obstetrics and Gynecology residents.
- I led creation of an ACGME accredited fellowship program in FPMRS at OUHSC in 2008.
- I created an on-line anatomy module for the 3rd year medical students rotating through OBG rotation at OU.
- I created a 4th year medical student research and clinical rotation in FPMRS.
- I have provided the leadership training courses to all rotating medical students during their third year OBG rotations.

II. Administrative:

2015— **Vice Chair**, Gynecologic subspecialties, Inova Fairfax Hospital, Falls Church, VA

2002-2015, **Division Chief**,

Female Pelvic Medicine and Reconstructive Surgery (FPMRS). The University of Oklahoma Health Sciences Center, Department of Obstetrics & Gynecology, Oklahoma City, OK

- I brought clinical and basic research in FPMRS to Oklahoma. I have been prolific in national and international meetings, and my number of publications has increased as a result of my ground breaking research in the area of 3D pelvic floor ultrasonography and levator ani anatomy.
- I created an educational curriculum for the Obstetrics and Gynecology residents and medical students.
- FPMRS fellowship achieved ACGME accreditation in January 2013.
- FPMRS achieved the **Center of Excellence** designation by the National Association For Continence (NAFC) in January 2013. The first in the Midwest and one of only 7 elite groups in the United States to achieve the Center of Excellence designation.

Curriculum Vitae

2002-2015, **Medical Director,**

OU Women's Pelvic & Bladder Health National Center of Excellence;
Continence Care

- I have directed the growth of this entity from one physician and one nurse to a core group of 30 faculty, staff and research members with extensive interaction with the other clinical services including but not limited to radiology, neurology, urology, colorectal surgery, and sonography.

Past experiences:

2002-15 Section chief, FPMRS, The University of Oklahoma HSC.
Created award winning programs in research, education, and clinical care over a 13 year period.

1988-1991 President
USM Company, Bellevue, WA

- I created and managed a multi-million dollar start-up corporation focusing on exports to Japan. I traveled extensively domestically and internationally for product selection, purchasing and securing contracts. I managed a team of independent contractors to finalize shipping and delivery.

1985 – 1988 Japanese interpreter and fleet maintenance manager
Arctic Ice Fisheries Corporation
Seattle, Washington.

- I built relationships between the Japanese and American deep-sea trawler captains in the Bering Sea and the Gulf of Alaska. I managed staff of 100+ to maintain fleet of 15 deep-sea trawlers.

1982 – 1985 Vice President, Marketing and Design
Japan AMA Corporation
Tokyo, Japan.

- I co-owned and managed a start-up corporation. Conformed to the international clients' needs to design consumer specific sports and casual clothing for export from Japan to Europe, Middle East and the United States.

III. Professional achievements

Oklahoma's first fellowship trained physician in Female Pelvic Medicine and Reconstructive Surgery / UROGYN 2002-15

Created a new section within the department of Ob/Gyn with a clinical operation that has grown to four fellowship trained physicians, Physician assistants, nurses, support staff, and research support 2002-15

Created Women's Pelvic & Bladder Health brand at the OU Physicians 2002-15

Created the Pelvic Floor Research Laboratory at OU 2002-15

Curriculum Vitae

Brought many multi-center clinical trials to OU, as well as other funding for original research	2002-
Created a syllabus and an educational course for OKC and Tulsa residents	2004-
Created an Anatomy workshop and an online anatomy module for MSIII and MS IV students in	2008
Created a suturing workshop and an online suturing course for MSIII and MS IV students in	2008
Created an MS IV elective in FPMRS	2008
Created OU WISH (Women's Incontinence and Sexual Health) support group in	2009
FPMRS fellowship program became accredited by ABOG/ABU	2009
Created Pelvic Floor Investigation Group (PFIG)	2009
Created International 3D Ultrasound Pelvic Floor Imaging Conference and workshops at OU	2010
Became an international research fellowship site for the IUGA and the ICS in 2010, with research scholars from Canada, India, Iran, Thailand, Mexico, Philippines, Europe and the US	2010
GYN Operating rooms transition leadership	2011
OUMC Six Sigma Committee	2011-2012
Created "Oklahoma Pelvic Floor Network" in 2012 as a gathering place for NP, PAs, FPs and PTs to learn about pelvic floor disorders	2012
OU LCME Review Committee	2012
Our FPMRS fellowship achieved ACGME accreditation January	2013
Our group achieved the National Center of Excellence designation by National Association for Continence,	January 2013
Created UROGYN Process Improvement Working Group	2013-15
OU Admissions committee	2013-15
OU Dept of Ob/Gyn Co-Chair promotions committee	2014-15
OU Leadership Development Institute Group leader	2014-15
TUFTS-Brandeis University executive management scholarship	2016-17

IV. Community service

Boston Healthcare for the Homeless	1992-1994
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Curriculum Vitae

Board of Directors, CASA, Oklahoma City	2007-8
Oklahoma City Food Bank	2002-15
OUHSC rowing team	2015

ii. SCHOLARSHIP

I. Publications

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76. **Shobeiri SA**, Chesson RR, West EC, Shott S, Hoyte L. *A Pilot Study of Extracorporeal Magnetic Stimulation of the Pelvic Floor for the Treatment of Women with Fecal Incontinence and Underactive Pelvic Floor Muscles*. J Pelvic Med Surg 2007;13(1):19-26.

Curriculum Vitae

77. **Shobeiri SA**, Nihira MA. *Management of total vaginal prolapse complicated by squamous papilloma*. J Pelvic Med Surg 2006;12:325-326.
78. **Shobeiri SA**. *Management of pelvic abscess after a Le Fort colpocleisis*. Int Urogyn Journal and Pelvic Floor Dys 17:668-669, 2006. PMID: 16520892
79. *Vardy M. D., Zhou H., **Shobeiri SA**. et al. *IVS Tunneler Device for apical vaginal prolapse with and without suburethral slingplasty: Preliminary safety report*. J Pelvic Med & Surg 12(2):107, 2006.
80. ***Shobeiri SA**. *An algorithm for management of post-operative voiding dysfunction after a trans-vaginal tape procedure for urinary incontinence*. J Pelvic Med & Surg 12(2):98-9, 2006.
81. Vakili B, Chesson RR, Kyle B, **Shobeiri SA**, Echols KT, Gist R, Zheng YT, Nolan TE. *The incidence of urinary tract injury during hysterectomy: A prospective analysis based on universal cystoscopy*. Am J of Obstet Gynecol 192:1599-604, 2005. PMID: 15902164
82. **Shobeiri SA**, Echols KT, Franco N. *Sinus formation after insertion of a silicone-coated suburethral sling*. International Urogynecology Journal and Pelvic Floor Dysfunction 14(5):356-357, 2003. PMID: 14618316
83. **Shobeiri SA**, Gasser RF, Chesson RR, Echols KT. *The Anatomy of Mid-Urethral Slings and Dynamics of Neurovascular Injury*. International Urogynecology Journal and Pelvic Floor Dysfunction 14(3):185-90, 2003. discussion 190. PMID: 12955340
84. **Shobeiri SA**, Chesson RR, Echols KT. *Cystoscopic Fistulography: A Review*. Urology Review Journal 1:20-1, 2003.
85. ***Shobeiri SA**, Chesson RR, Echols KT. *Three-Dimensional MRI Anatomy of Fecal Incontinent Female Patients Compared to Normal Individuals*. J of Pelvic Med & Surg 9(5): 222, 2003.
86. ***Shobeiri SA**, Chesson RR, Gasser RR. *The Internal Innervation and Morphology of the Female Human Iliococcygeus and Pubococcygeus muscles: Preliminary Results from a New Technique*. J of Pelvic Med & Surg 9(5): 209, 2003.
87. ***Shobeiri SA**, Chesson RR, Echols KT. *Establishing Competency Parameters for the Obstetrics and Gynecology Residents' Diagnostic Cystoscopy Education*. Obstet Gynecol 101(Supp. 4): S113-114, 2003.
88. ***Shobeiri SA**, Chesson RR, Echols KT. *Establishing Competency Parameters for the Obstetrics and Gynecology Readers' Diagnostic Cystoscopy Education*. Obstet Gynecol 101(Supp. 4): S113-114, 2003.
89. Franco N, **Shobeiri SA**, Echols KT. *Validated Simplified Urinary Incontinence Score for the Medium-term Evaluation of Transvaginal Pubovaginal Sling Procedure*. UROLOGY 60:607-10, 2002. discussion 610-1. PMID: 12385917
90. **Shobeiri SA**, Nolan TE, Yordan-Jovet R, Echols TE, Chesson RR. *Digital Examination Compared to Trans-Perineal Ultrasound for the Evaluation of Anal Sphincter Repair*. International Journal of Gynecology & Obstetrics 78(1):31-36, 2002. PMID: 12113968

Curriculum Vitae

91. **Shobeiri SA**, Garely AD, Chesson RR, Nolan TE. *Recognition of Occult Bladder Injury during the Tension-Free Vaginal Tape Procedure*. Obstetrics & Gynecology 99(6):1067-72, 2002. PMID: 12052601
92. Echols KT, Chesson RR, Breaux EF, **Shobeiri SA**. *Persistent Delayed Hypersensitivity Following Transurethral Collagen Injection for Recurrent Stress Urinary Incontinence: A Case Report*. International Urogynecology & Pelvic Floor Dysfunction Journal 13:52-54, 2002. PMID: 11999209
93. **Shobeiri SA**, Chesson RR, Echols KT. *Cystoscopic Fistulography: A New Technique for the Diagnosis of Vesicocervical Fistula*. Obstetrics & Gynecology 98(6):1124-6, 2001. PMID: 11755564
94. ***Shobeiri SA**, Chesson RR. *Magnetic Stimulator for the Treatment of Fecal Incontinence*. Int Urogyn J 12(Supp. 3):S100-101, 2001. Neurourology & Urodynamics 20(4), 2001.
95. ***Shobeiri SA**, Chesson RR. *The Mid-Urethral Sling Anatomy*. International Urogynecology J 12(Supp. 3): S19-20, 2001.
96. **Shobeiri SA**, West EC, Kahn M, Nolan TE. *Postpartum Acquired Hemophilia (Factor VIII Inhibitors): A Case Report and Review of the Literature*. Obstetrical & Gynecological Survey 12(55):729-37, 2000. PMID: 11128909
97. **Shobeiri SA**, Elkins TE, Thomas KA. *Comparison of Sacrospinous Ligament, Sacrotuberous Ligament, and 0 Polypropylene Suture Tensile Strength*. J Pelvic Surgery 6:261-7, 2000.

Submissions

98. Shobeiri SA. Lean-Six sigma; A Center of Excellence Experience. In progress.
99. Shobeiri SA. Aligning medical students with academic institution goals. In Progress.
100. Shobeiri SA, White DE, Rostaminia G. 5 year review of a successful international ultrasound workshop. In progress.
101. Javadian P, Shobeiri SA. 10 year review of an anal sphincter repair workshop for Obstetrics and Gynecology residents. In progress.
102. Meyer I, Quiroz LH, **Shobeiri SA**. *Intraoperative suprapubic pressure test for prevention of de novo stress urinary incontinence after correction of pelvic organ prolapse*. Submitted.
103. Meyer I, Quiroz LH, Nihira MN, **Shobeiri SA**. *Medium to long-term outcomes of the anterior Hammock procedure using autologous fascia lata*. Submitted.
104. **Shobeiri SA**, Quiroz LH, Santoro GA et al. *Pelvic Floor Phantoms: A Step Forward in Teaching Hands-on Pelvic Floor Sonography to a Large Group of Participants*. Submitted.
105. Manonai J, Shobeiri SA. Levator plate architecture and anal complex in women with or without fecal incontinence. In progress.

Curriculum Vitae

106. Shobeiri SA. Relative contributions of the levator ani subdivisions to levator ani movement. In progress.
107. Rostaminia G, Quiroz LH, Shobeiri SA. Levator ani muscle deficiency and the influence of age and parity. Submitted
108. Javadian P, Shobeiri SA. Ultrasonic predictors of mesh complications. In progress.
109. Javadian P, Shobeiri SA. Trans-obturator tape syndrome: Ultrasonic Predictors of Pain. In progress.
110. Javadian P, Shobeiri SA. Comparison of in-person vs internet based Anatomy module for third year medical students. In progress.
111. Javadian P, Shobeiri SA. Public Health Impact of Vaginal Mesh Complications on Women's Health. In progress.

II. Books and book chapters

Ambulatory Urology and Urogynecology 2017

Editor: Ajay Rane, MD, Wiley Publishers 2017

- ❖ Pelvic floor Anatomy, **Shobeiri SA**
- ❖ Pelvic floor trauma, Rostaminia G, **Shobeiri SA**
- ❖ Pelvic floor ultrasound, Denson LE, **Shobeiri SA**
- ❖ Injection Therapy for stress urinary incontinence, **Fatehchehr S, Shobeiri SA**
- ❖ Classification of Meshes, Stone D, **Shobeiri SA**
- ❖ Anatomy of Female Urethra, Santiago A, **Shobeiri SA**

Childbirth Trauma 2017

Editor: Stergios Doumouchtsis,
Springer publishers, in publication 2016.

- ❖ Epidemiology of Childbirth Trauma
Lieschen H. Quiroz, and **S. A. Shobeiri**
- ❖ Ultrasonography of Childbirth Trauma
Ghazaleh Rostaminia, and **S. A. Shobeiri**

Practical Pelvic Floor Ultrasonography (2nd Edition)

Editor: S. Abbas Shobeiri, Springer Publishers 2017

- ❖ Endovaginal Ultrasonography, **Shobeiri SA**

Anorectal and Pelvic Floor Ultrasonography

Editor: Lucia Oliveira and Sthela Regadas, Wiley Publishers 2016

- ❖ Endovaginal Ultrasonography, **Shobeiri SA**

Seminars in Colon and Rectal Surgery

Editor: Anders Mellgren, Wiley Publishers 2016

- ❖ Management of Pelvic pain, Javadian P, **Shobeiri SA**

Current Obstetrics and Gynecology 2015

Section Editor, **Shobeiri SA.**

- ❖ Review of Pelvic floor trauma and its relationship to Pelvic Organ Prolapse,
Benjamin Barenberg and Lieschen H. Quiroz
- ❖ Review of Vaginal Mesh complications in Pelvic Organ Prolapse surgeries,

Curriculum Vitae

Pouya Javadian and Dena O'Leary

- ❖ Review of Uterine morcellation use in Pelvic Organ Prolapse surgeries, Soorena Fatehcher and Ceana Nezhat

- ❖ Review of Pelvic floor ultrasound imaging in Pelvic Organ Prolapse, Andrea Santiago and **SA Shobeiri**

- ❖ Review of Advances in surgical treatment of Fecal Incontinence, Isuzu Meyer and Holly Richter

- ❖ Review of 3D Modelling and Pelvic Organ Prolapse, Ghazaleh Rostaminia and Steven Abramovitch

Principles and Practice of Urogynaecology 2015

Editors: Arjunan Tamilselvi & Ajay Rane

2015, XIV, 178 p. 77 illus., 61 illus. in color.

Springer India, Publication 2015, pp 17-22,

ISBN 978-81-322-1692-6, DOI 10.1007/978-81-322-1692-6_2,

- ❖ Neuroanatomy of the Female Pelvis,

Pickett S, **Shobeiri SA**.

Practical Pelvic Floor Ultrasonography 2015

Editor: **S. A. Shobeiri**,

Springer publishers, 2014.

237 p. 302 illus., 261 illus. in color.

ISBN: 978-1-4614-8425-7

(Print) 978-1-4614-8426-4 (Online),

DOI 10.1007/978-1-4614-8426-4

- ❖ Introduction

S. Abbas Shobeiri

- ❖ Pelvic Floor Anatomy

S. Abbas Shobeiri

- ❖ 2D / 3D Endovaginal & Endoanal Instrumentation and techniques

S. Abbas Shobeiri

- ❖ Instrumentations and Techniques for Transperineal and Translabial Pelvic Floor Ultrasound

Milena Weinstein & **S. Abbas Shobeiri**

- ❖ 3D Endovaginal Ultrasound Imaging of the Levator Ani Muscles

Lieschen H. Quiroz & **S. Abbas Shobeiri**

- ❖ Endovaginal Imaging of the Urethra and the Bladder

A. Pawel Wieczorek & Magdalena M. Wozniak

- ❖ Endovaginal Imaging of the anorectal structures

Dena White & **S. Abbas Shobeiri**

- ❖ Endovaginal Imaging of Vaginal implants

Aparna Hegde & G. Willy Davila

- ❖ Endovaginal Imaging of Pelvic Floor Cysts and Masses

Ghazaleh Rostaminia & **S. Abbas Shobeiri**

- ❖ Endoanal Ultrasonography of the Anorectal Region

Giulio A. Santoro & Sthela Murad-Regadas

- ❖ Endoanal Ultrasonography of the Anorectal Cysts and Masses

Sthela Murad-Regadas & Giulio A. Santoro

- ❖ Emerging Pelvic Floor Technologies and Techniques

S. Abbas Shobeiri & Jittima Manonai

- ❖ Post-Test on Pelvic Floor Imaging

S. Abbas Shobeiri

International Academy of Pelvic Surgery 2011

Walters, M., Karram, M. Eds. Online Publication: June, 2011

Curriculum Vitae

❖ *Simulation and Gynecologic Surgery: A Complementary Teaching Approach to the "See One, Do One, Teach One" Method for Surgical Training.*
Nihira, MA and **Shobeiri, SA.**

Pelvic Floor Disorders 2010

Editor: Giulio A. Santoro, MD, PhD and Pawel Wieczorek, MD
Springer publishers, October 14, 2010 | ISBN-10: 8847015413 | ISBN-13: 978-8847015418 |
Edition: 2010

❖ *Advances in our understanding of pelvic floor anatomy.* PP 3-16

John O. DeLancey and **S. A. Shobeiri, MD.**

❖ *Endovaginal three Dimensional Sonography.* PP 61-78

Giulio Santoro, MD, Pawel Wieczorek, MD, and **S. A. Shobeiri, MD.**

❖ *Imaging Complications of Urogynecological Surgery in a New Age.* PP 695-710
S. A. Shobeiri, MD.

Muscular System - Anatomy, Functions and Injuries 2008

❖ *Anal sphincter damage and childbirth mechanism of action, diagnosis and treatment.*

NOVA publishers,

ISBN: 978-1-62100- 2010, PP 190-4

Francesca Sartori, Giulio Santoro, **S. A. Shobeiri.**

Atlas of the Urologic Clinics of North America 2003

❖ *Uterosacral Suspension of the Vaginal Vault.*

Volume 11, Issue 1, Pages 113-127, April 2003 PP 113-117.

R. R. Chesson, MD, **S. A. Shobeiri, MD.**

iii. FUNDING

I. Local

Negotiated funding for OU Women's and Pelvic Bladder Health Center

Negotiated creation of Women's surgical suites at OU Medical Center

Created OU Women's Pelvic Medicine Fund

Negotiated funding for faculty and fellows

Raised funds after a friend died of Melanoma to dedicate a conference room at the OU cancer center to her name.

II. Research funding pending

NIH NICHD (Submitted) Pelvic Floor Disorders Network Clinical Sites

PI

2016-2021 15% effort

NIH NICHD R21 (Submitted) Structural and Inflammatory Basis of Levator Ani Regeneration

PI

2016-2018 20% effort

III. Funded Research

VTI Phase IV Research

NIA

Curriculum Vitae

PI: Vladimir Egorov, PhD, Artann Laboratories Inc.

NIH NICHD 1U01HD077384-01A1: Optimizing Management of the 2nd Stage (OMSS): a Multicenter Trial

Consultant / Co-investigator, PI: Alison Cahill, MD, Washington University
2014-2018 10% effort

The TRUST study (Treatment Results of Uterine Sparing Technologies) U.S.A. Study”
Halt Medical Inc. \$383,910.00
PI

07/06/2015 – 05/31/2016 5% effort

NIH NIAID Cooperative Centers for Research in Human Immunology Program grant number
U19AI062629 Innate Immune Response upon West Nile Virus Infection of Human Skin
Co-investigator, PI: Jose Alberola, PhD (OU). Mark Coggeshall, PhD (Stanford)
2015-2016 3% effort

NIH NIDDK 5P20DK097799-02: The Role of Altered Permeability in Bladder Diseases
Co-investigator, PI: Robert Hurst, PhD
2014-2015 5% effort

NIH NIAID U19 AI6262: Development of a human skin explant model for modeling cutaneous
bacterial infection
Co-investigator, PI: Susan Kovats, PhD
2014-2015 5% effort

ACELL Study
Randomized multicenter trial of Matristem vs. native tissue repair
Co-investigator
2014- 5% effort

International Urogynecologic Association (IUGA) 2013 research scholar award
Andrea Santiago, MD, Philippines

International Continence Society (ICS) 2013 Research Scholar award
Jittima Manonai, MD, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand

American Urogynecologic Society (AUGS Foundation grant)
“The greatest risks of obstetrics trauma during childbirth”
Co-investigator
2012-2014, 5% effort

(ACOG) American College of Obstetricians and Gynecologists Kenneth Gottsfeld-Charles
Hohler Memorial Foundation Research Award in Ultrasound
“Effects of childbirth on the pelvic floor of women”
Co-investigator
2012-2014, 5% effort

AUGS 2011 Thomas Benson award
“Findings at Peripheral Nerve Evaluation: What is the significance of levator ani muscle
status?”
2012-Present, 5% effort

OU Clinical and Translational Sciences Scholar Program 2011
Melissa Muhlinghouse,

Curriculum Vitae

AUGS 2010 Thomas Benson award

"Vaginal Electrical Stimulation vs. Sacral Neuromodulation for the Treatment of Refractory Overactive Bladder: A Pilot Study"

2011-Present, 5% effort

TRANSFORM Study

"An investigation of the Treatment of Fecal Incontinence Using the TOPAS Sling System For Women (TRANSFORM)"

4/2010-2013

OU Clinical and Translational Sciences Scholar Program 2010

Jordan Brady,

BK Medical Inc. PI,

Histological correlative study of Pelvic floor to 3D Ultrasonography

OU College of Medicine Alumni Foundation Grant

Effect of aging on the levator ani muscles

Co-investigator

Uroplasty, Inc.

Study of Urgent PC Versus Sham Effectiveness in Treatment of Overactive Bladder Symptoms.

A Multicenter trial

Co-investigator

9/10/2008 - 9/9/2011

Uroplasty, Inc.

Macroplastique Real-Time Observation of Safety and Effectiveness in the Treatment of Female Stress Urinary Incontinence - Rose Registry A Multicenter trial

Co-investigator

2/4/2008 – 2/3/14

BK Medical Inc.

3D ultrasonography of pelvic floor muscles

Principle Investigator

Uroplasty Inc.

Detrol vs. pretibial nerve stimulation trial. A Multicenter trial

Co-investigator

U.S. Surgical

Evaluation of posterior intravaginal slingplasty. A Multicenter trial

Co-investigator

Interstim Bowel Control: Fecal Incontinence Study

A Multicenter trial

Co-investigator

2003

National Institute of Health Loan Repayment Program

2003-2005

American Medical Systems

Trial of BioArch anti-incontinence device. A Multicenter trial

Co-investigator

Curriculum Vitae

2003

Neotonus Inc.
Magnetic Resonance Imaging of the Levator Ani Muscles
Principle Investigator
2001

iv. TEACHING

I. Presentations

1) International

European Pelvic Floor Therapy Symposium: Keynote speaker
Pelviusse-Symposium
Winterthur, Switzerland,
November, 14, 2015

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Continence Society
Montreal, Canada
October, 2015

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Urogynecological Association
Niece, France
June, 2015

How to create an award winning pelvic floor center, round table presentation
International Urogynecological Association
Niece, France
June, 2015

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Continence Society
Rio, Brazil
October, 2014

Posterior Compartment Dysfunction Workshop: Presenter
International Continence Society
Rio, Brazil
October, 2014

Recognition and management of Obstetric fistulas: Presenter
International Continence Society
Rio, Brazil
October, 2014

IUGA/AUGS Scientific Meeting
How to create an award winning pelvic floor center, round table presentation
Washington DC, USA
July, 2014

Curriculum Vitae

IUGA/AUGS Scientific Meeting

Pelvic floor repair using autologous harvest, round table presentation
Washington DC, USA
July, 2014

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman

International Urogynecological Association
Washington DC, USA
July, 2014

Posterior Compartment Dysfunction Workshop: Presenter

International Urogynecological Association
Washington DC, USA
July, 2014

Fistulas in developing and developed countries: Presenter

International Urogynecological Association
Washington DC, USA
July, 2014

IUGA Regional Conference,

International Urogynecological Association
Pubococcygeal avulsion, Myth or reality
Quality of life Inventories in urogynecology which ones to use
Defecatory dysfunction
Conventional imaging in pelvic floor disorders
Bogata, Columbia
February 2014

IUGA Regional Conference, Featured Speaker

International Urogynecological Association
Management of Mesh Complications
Role of Transperineal and Endoanal Ultrasound
OAB: Approach and Management
Hyderabad, India
November 2013

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman

International Continence Society
Barcelona, Spain
September 2013

Posterior Compartment Dysfunction Workshop: Presenter

International Continence Society
Barcelona, Spain
September 2013

Recognition and management of Obstetric fistulas: Presenter

International Continence Society
Barcelona, Spain
September 2013

Frontiers of Pelvic Floor Imaging: Featured Speaker

Comprehensive 3D Ultrasound imaging of pelvic floor workshop
State of the art pelvic floor imaging
Round table discussion: Levator ani repair

Curriculum Vitae

Mexican Urogynecologic Society Meeting
Mexico City, Mexico
June 2013

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Urogynecological Association
Dublin, Ireland
May 2013

Posterior Compartment Dysfunction Workshop: Presenter
International Urogynecological Association
Dublin, Ireland
May 2013

Recognition and management of Obstetric fistulas: Presenter
International Urogynecological Association
Dublin, Ireland
May 2013

Advances in Pelvic Floor Imaging, What Does It Mean? Featured Speaker and panel discussion
56th All India Congress of Obstetrics and Gynecology
Mumbai, India
January 2013

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
Posterior Compartment Dysfunction workshop: Speaker
International Continence Society
Beijing, China
October 2012

Frontiers of Ultrasound Pelvic Floor Imaging, IUGA Fellows' Forum: Chairman
International Urogynecological Association,
Brisbane, Australia
September 2012

Comprehensive 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Urogynecological Association
Brisbane, Australia
September 2012

Pelvic Floor Imaging and Research
Collaborative OU and Croydon University Hospital Research Group
London, England
February 2012

Endoanal Ultrasonography for Ob/Gyn: Featured speaker
Role of Ultrasonography in Pelvic Floor: Featured speaker
Evaluation of Mesh Complications in Pelvic Floor Surgery
International Federation of Gynecology and Obstetrics
FIGO Working Group on Pelvic Floor Medicine and Reconstructive Surgery meeting and The
Royal Thai College of Obstetricians and Gynecologists
Bangkok, Thailand
November 2011

3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman

Curriculum Vitae

International Continence Society,
Glasgow, England
September 2011

3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
Posterior Compartment Dysfunction
International Urogynecological Association
Lisbon, Portugal
June 2011

Imaging Complications of Urogynecological Surgery: Featured Speaker
50th FOCUS in Obstetrics and Gynecology
Hong Kong
June 2011

Advanced Pelvic Floor Imaging,: Featured Speaker
Hong Kong Urogynecological Association Meeting
Hong Kong
June 2011

State of the Art Pelvic Floor Imaging: Featured Speaker
Controversies in Ob/Gyn: Why Doesn't Mesh Always Work
Controversies in Ob/Gyn: Anatomy and Function of the Anal Sphincter
Annual clinical meeting of ACOG
Mexico City, Mexico
June 2011

Anatomy of the Anterior Compartment
American Society of Colorectal Surgeons
Vancouver, Canada
May 2011

Surgical Interventions for Pelvic Organ Prolapse
Advanced Pelvic Floor Anatomy and Ultrasound Imaging
Treviso Ultrasound Symposium
Treviso, Italy
November 2010

Case studies in 3D Ultrasound Pelvic Floor Imaging
BK Symposium
Copenhagen, Denmark
November 2010

State of the Art Pelvic Floor Imaging
Spanish Hospital
Mexico City, Mexico
October 2010

3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman
International Continence Society
Toronto, Canada
August 2010

Ultrasound Imaging of Pelvic Floor Anatomy
Ultrasound Symposium
Krakow, Poland

Curriculum Vitae

June 2010

Imaging Complications of Urogynecological Surgery: Featured Speaker
12th annual Japanese Pelvic Medicine Society
Omiya, Japan
May 2010

Pelvic Floor Anatomy
Hacettepe University Medical Center
Ankara, Turkey
March 2004

The Anatomy and Function of the Female Genitourinary Tract
Saitama University, Department of Obstetrics & Gynecology
Saitama, Japan
August 2001

2) National

Pelvic Floor Disorders week
Practical aspects of pelvic floor ultrasonography, Ultrasound workshop
American Urogynecological society
Seattle, WA
October 2015

Pelvic Floor Disorders week
How to incorporate Ultrasonography into your practice
American Urogynecological society
Seattle, WA
October 2015

Pelvic Floor Ultrasound
Seattle Gynecological Society
Seattle, WA
September 2015

Management of mesh complications
Seattle Gynecological Society
Seattle, WA
September 2015

2D and 3D Multicompartmental Ultrasound Imaging of Pelvic Floor Workshop: Chairman
Society of Gynecological Surgeons' Annual Meeting
Hollywood, Florida
March, 2015

Transperineal vs endovaginal 3D Ultrasound Imaging of Pelvic Floor Workshop: Chairman,
Co-Chair: Phyllis Glanc, MD, Associate Professor of Radiology, The University of Toronto
American Institute of Ultrasound in Medicine Annual Meeting
Hollywood, Florida
March, 2015

Pharmacologic Treatments for Urogynecologic Conditions
Inova Fairfax Hospital, Virginia
February, 2015

Curriculum Vitae

Regional Professional Coders Association
Business Aspects of running a continence program
Oklahoma City, OK
November, 2014

The University of North Carolina
Ultrasound Imaging of Pelvic Floor Workshop: Chairman
Durham, NC
December, 2013

Imaging of Pelvic Floor Disorders, Session Moderator
American Urogynecologic Society
Chicago, IL
September 2012

Incorporating 3D Ultrasound imaging into your practice, round tables
Intraoperative 3D Ultrasound imaging of pelvic floor, Fellows' lecture series
American Urogynecologic Society
Providence, Rhode Island
September 2011

Advanced Pelvic Floor Imaging
Cleveland clinic Ultrasound Imaging symposium
Cleveland Clinic, FL
March 2011

3D Ultrasound Imaging of Pelvic Floor Workshop
73rd annual University of Minnesota Colorectal Surgery
Minneapolis, MN
October 2010

3D Ultrasound Imaging of Pelvic Floor – One Day Workshop: Chairman
International Continence Society
San Francisco, CA
May 2009

Pelvic Floor Dysfunction and the Use of Botox
Seattle Gynecological Society
Seattle, WA
September 2006

How to Prepare a Poster Presentation
American Urogynecological Society Fellows' Research Retreat
April 2006

How to Build Specific Aims and Hypothesis
American Urogynecological Society Fellows' Research Retreat
April 2006

The Anatomy of the Female Bladder and the Urethra
Baylor University Medical Center
Dallas, TX
June 2001

Female Pelvic Medicine...What is it?

Curriculum Vitae

Tulane University School of Medicine
New Orleans, LA
May 2001

The Overactive Bladder, Advancements and Disappointments
Louisiana State University Health Sciences Center
New Orleans, LA
June 2000

Preoperative, Intraoperative & Postoperative Complications
New Orleans Ob/Gyn Board Review course
2000, 2001, 2002

Adnexal Masses,
New Orleans Ob/Gyn Board Review course
May 2000

Hysterectomy
New Orleans Ob/Gyn Board Review course
May 2000

Anatomy Course Proctor
American Urogynecological Society
New Orleans, LA
March 2000, April 2001, April 2003

Pelvic Anatomy Lab Proctor
Second year Anatomy course
Louisiana State University Medical School
1999, 2000

Chronic Pelvic Pain
Grand Rounds
Louisiana State University Health Sciences Center
April 1999

3) Regional

Inova Leadership Development Institute
Falls Church, VA
November 2015

OU Leadership Development Institute
Surgical Care NOS, Round table facilitator
Oklahoma City, Oklahoma
February 2014

Pelvic Floor Dysfunction
Tulsa Ob/Gyn Society
Tulsa, Oklahoma
September 2007

Evidence Based Cystoscopy for Practicing Ob/Gyn
Tulsa Ob/Gyn Society
Tulsa, Oklahoma

Curriculum Vitae

July 2005

The Overactive Bladder Syndrome
The American Academy of Family Physicians
Oklahoma City and Tulsa, Oklahoma
February 2005

Female Pelvic Medicine and Reconstructive Surgery
Tulsa Ob/Gyn Society
Tulsa, Oklahoma
February 2005

4) Local

Correlative Gynecologic anatomy
Inova Fairfax resident lecture series
December 2015

Art and Medicine interest group Invited speaker
The University of Oklahoma Health Sciences Center
March 2014

The Painful Bladder Syndrome and the Unseen Etiologies of CPP
The University of Oklahoma Pain Symposium
May 2009

Pudendal Neuropathy
The University of Oklahoma Health Sciences Center Grand rounds
Oklahoma City, Oklahoma
March 2009

Pudendal Neuropathy
Oklahoma City Ob/Gyn Society
Oklahoma City, Oklahoma
August 2008

Peripheral Neuropathy in Gynecologic Surgery
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
May, 2008

Embryologic Basis of Vaginal Agenesis
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
March 2008

The Painful Bladder Syndrome and the Unseen Etiologies of CPP
The University of Oklahoma Pain Symposium
Oklahoma City, OK
March 2007

Urinary Incontinence
The University of Oklahoma Primary Care Conference
Oklahoma City, OK
May 2006

Curriculum Vitae

The Unseen Pathologies of the Pelvic Nervous System
MERCY Hospital
Oklahoma City, Oklahoma
March 2006

The Pathophysiology of the Overactive Bladder Syndrome
The University of Oklahoma Family Practice Grand Rounds
Oklahoma City, Oklahoma
May 2005

Physical Therapist's Treatment of the Female Pelvic Floor
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
April 2004

Physical Therapist's Evaluation of the Female Pelvic Floor
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
January 2004

Applied anatomy for Pelvic Floor Rehabilitation
Oklahoma Physical Therapy Association Meeting
October 2003

The Overactive Bladder
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
November 2002

The Unseen Pathologies of the Pelvic Nervous System
The University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma
October 2002

5) Abstract presentations

International

International Continence Society
Barcelona, Spain – 2013

1. Effects of the first vaginal delivery in women early postpartum versus years remote from delivery
2. 3-dimensional endovaginal ultrasound can reliably detect normal anal sphincter anatomy
3. Predictors of anal incontinence in the absence of anal sphincter defect
4. Sonographic predictors of obstructive defecatory dysfunction
5. Relative contributions of the levator ani subdivisions to levator ani movement

37th Annual Meeting of the International Urogynecologic Association
Brisbane, Australia – 2012

1. Comparison of 3D endovaginal ultrasound to magnetic resonance imaging of the pelvic floor musculature
2. How much levator muscle defect is associated with female pelvic organ prolapse?
3. Does the visualization of pelvic floor structures change with age?
4. Borders of the minimal levator hiatus and their relationship to the puborectalis muscle and the levator plate

Curriculum Vitae

5. The visualization of urethral muscles is not associated with continence status in patients with prolapse
6. Levator plate angle: a new measure that demonstrates levator plate descent correlates with poor levator muscle status
7. Open versus minimally invasive sacrocolpopexy: a comparison of de novo urinary symptoms

36th Annual Meeting of the International Urogynecologic Association
Glasgow, Scotland – 2011

1. 3D Ultrasound anatomy of the female pelvic floor, a direct histologic comparison: anterior and posterior compartments
2. Age effects on pelvic floor symptoms in a cohort of nulliparous patients

National

41st Annual Society of Gynecology Surgeons Meeting
Orlando, FL – 2015

1. Risk factors of lower urinary tract injury at the time of prolapse and incontinence repair

35th Annual Meeting Society of Maternal-Fetal Medicine
San Diego, CA - 2015

1. Performance of the fasting glucose value alone for diagnosing gestational diabetes and predicting neonatal adiposity

62nd Annual Meeting of the Pacific Coast Reproductive Society
Rancho Mirage, CA – 2014

1. Initiating infertility treatment: does it improve or worsen anxiety and/or depression?
2. The acceptance and donation of fertility medications: examining the frequency and protocols in place across United States fertility clinics
3. Does fertility treatment affect marital satisfaction? A pilot study.

AUGS/IUGA Joint Annual Scientific Meeting
Washington, DC – 2014

1. Complications during mesh removal and patient-based outcomes after mesh removal
2. Decreased urethral volume on 3-D endovaginal ultrasound is comparable to bladder neck funneling on fluoroscopy as a predictor of intrinsic sphincter deficiency
3. Is there a correlation between levator ani deficiency and urethral sphincter complex measurements on 3-D endovaginal ultrasound?
4. Multicompartmental ultrasound approach to anorectal dysfunction

34th American Urogynecologic Society Annual Scientific Meeting
Las Vegas, NV – 2013

1. Are there sonographic predictors of obstructive defecatory symptoms?
2. Can 3-dimensional ultrasound detect normal anal sphincter anatomy?

38th Annual Society of Gynecologic Surgeons Meeting
Baltimore, MD – 2012

1. The influence of obesity on complication rates following benign hysterectomy
2. Outcomes of minimally invasive and abdominal sacrocolpopexy: A Fellows' Pelvic Research Network Study

33rd American Urogynecologic Society Annual Scientific Meeting
Chicago, IL – 2012

1. Interrater reliability of 3D endovaginal ultrasound anatomy of asymptomatic nulliparous women based on direct histologic comparison: anterior and posterior compartments

32nd American Urogynecologic Society Annual Scientific Meeting

Curriculum Vitae

Providence, RI – 2011

1. Does the visualization of pelvic floor structures change with age?
2. Incidence of unanticipated uterine pathology at the time of minimally invasive sacrocolpopexy
3. 3D Ultrasound anatomy of the female pelvic floor, a direct histologic comparison: anterior and posterior compartments
4. Age effects on pelvic floor symptoms in a cohort of nulliparous patients

31st American Urogynecologic Society Annual Scientific Meeting (Fellows Forum)
Long Beach, CA – 2010

1. Vaginal mesh complications in the community: the experience of a university-based urogynecology practice

II. Videos and media presentations

Implications of FDA warning on morcellation complications. KWTN Newscast, Oklahoma City 2014

Implications of FDA warning on vaginal mesh kit complications. KWTN Newscast, Oklahoma City 2014

Fascia Lata Hammock Procedure AUGS / IUGA 2014 Barenberg, B. Shobeiri SA,
Posterior Compartment 3D Ultrasound Imaging AUGS / IUGA 2014 Santiago A, Shobeiri SA
Oklahoma Live, KSBI 52, featured local artist, Oklahoma City 2013

Urethral bulking agents KOTV TV Newscast, Oklahoma City 2004

Pudendal Neuralgia KOCO TV Newscast, Oklahoma City 2006

Pelvic pain KOCO TV Newscast, Oklahoma City 2007

Interstim therapy KFOR TV Newscast, Oklahoma City 2003

III. Teaching Materials Developed

2009 -- Present Ultrasound module for ultrasonography students

2014- Working group to develop Anatomy modules for first year medical
students

2010 – Present Pelvic Floor Ultrasound Phantom – currently working with an external
vender to commercially produce the models

2008 – 2013 Third year Medical student suturing course

2010 – Present Third year Medical student professionalism course / AIDET

2008 – Present Third year Medical student pelvic anatomy course

2006 – Present Workshop for the repair of 3rd and 4th degree Obstetric lacerations

2005 – 2010 Blackboard for teaching Urogynecology

2002 – Present Teaching anatomy to 1st year Medical students

2002 – Present Urogynecology teaching core curriculum

IV. Creative Achievements

Curriculum Vitae

1999 - Present	I have created new procedures and surgeries for evaluation and treatment of pelvic floor disorders including a collaborative patent development agreement for an ultrasound phantom
2012	BJOG (British Journal of Obstetrics and Gynecology) top Reviewer
2010	APGO Excellence in Teaching Award
2010	AUGS, Best Educational Research Award
2007 – 2013	Medical student teaching awards
1999	Resident Research Award, <i>Utilization of ultrasonography for the evaluation of anal sphincter repair</i>

V. Resident Mentees

1. Buchinger, D, Shobeiri, SA. Is cervical dilation a predictor of post-partum urinary incontinence: A comparison of patients undergoing cesarean section versus vaginal delivery? June, 2006.
2. LeClaire E, Shobeiri SA. 3D Anatomy of pelvic Floor Muscles. June 2007.
3. D. Nelson Fong, MD, Advisor: S. Abbas Shobeiri, MD, A Standard Method of Primary Obstetric Anal Sphincter Repair, 2009.
4. D. Nelson Fong, MD, Advisors: S. Abbas Shobeiri, MD; Lieschen Quiroz, MD; Mikio Nihira, MD; Arielle Allen, MD, Obstetric Anal Sphincter Laceration Repair in the United States: Is there a Common Practice Pattern? 2010
5. Isuzu Meyer, M.D., Advisor: S. Abbas Shobeiri, M.D., Determinants of Occult Stress Urinary Incontinence after Correction of Prolapse, 2010
6. Isuzu Meyer, MD PGY 4, Lieschen Quiroz, MD, S. Abbas Shobeiri, MD. Effects of Childbirth on Pelvic Floor Muscle Strength 2012
7. Juarez, Dianna, PGY 4, LeClaire, Edgar L., Quiroz, Lieschen H., Mukati, Marium S., White, Dena, Shobeiri SA, Abdominal vs. Minimally-Invasive Sacrocolpopexy: A Comparison of *de novo* Stress Urinary Incontinence Outcomes, 2012
8. Wesley Vaughn, PGY 3, S. Abbas Shobeiri, MD. The psychosocial behavior pattern of the residents and faculty at OUHSC OB/GYN dept. 2014
9. PGY2, 3rd and 4th degree laceration repair training program. Is there a deficit?

VI. Post-doc Mentees

2015-	Wang Li, MD, China, FPMRS research scholar Mentored in conduct of research
2014-	Pouya Javadian, MD, Iran, FPMRS research scholar Mentored in conduct of research, MS thesis: Public Health impact of surgical intervention
2011 – 2014	Ghazaleh Rostaminia, MD, Iran, FPMRS research scholar Mentored in conduct of research, MS thesis in 3D Finite element modelling, 3D pelvic floor Ultrasonography.
2011 – 2013	Marium Mukati, MD, USA, FPMRS research scholar Mentored in conduct of research.
March 2013	Joshua Yune, MD, USA, FPMRS fellow, Loma Linda University Mentored in conduct of research, 3D pelvic floor Ultrasonography.

Curriculum Vitae

March 2012 Parifar Rostami, MD, Canada, FPMRS research observer
Mentored in conduct of research.

November 2011 Elena Tunitsky, MD, USA, FPMRS fellow, Cleveland Clinic
Mentored in conduct of 3D pelvic floor Ultrasonography.

2011 - 2013 Kim Van Delft, MD, Denmark, Croydon University, UK fellow
Mentored in conduct of research, PhD thesis in 3D pelvic floor Ultrasonography.

May 2012 Aparna Hegde, MD, India, (IUGA) Research scholar
Mentored in conduct of research in 3D pelvic floor Ultrasonography.

January 2013 Samaneh Sehat Baksh, MD, Iran, Research observer
Mentored in conduct of research.

April – June 2013 Jittima Manonai, MD, Thailand, International Continence Society (ICS) Research scholar
Mentored in conduct of research, 3D pelvic floor Ultrasonography.

2013 - 2015 Andrea Santiago, MD, Philippines, International Urogynecological Association (IUGA) Research scholar
Mentored in conduct of research, 3D pelvic floor Ultrasonography.

2013 - Present Lindsay Denson, RDMS, USA, "MPH" Research Scholar
Mentored in conduct of research, MS thesis in 3D pelvic floor Ultrasonography investigation of pelvic floor injury with vaginal delivery.

2014 - Present Pouya Javadian, MD, Iran, FPMRS research fellow

July - October 2013 Daniel Velez, MD, Mexico, "PhD" FPMRS Research scholar
Mentored in conduct of research, PhD thesis in 3D pelvic floor Ultrasonography and perineal injury associated with vaginal delivery.

2009 – 2012 Arielle Allen, DO, FPMRS fellow
Mentored in conduct of research, MS thesis in the role of VGEF and PDEF in cystitis in a mouse model.

2010 – 2013 Dena White, MD, FPMRS fellow
Mentored in conduct of research, MS thesis in the role of cytokines, IL6 transgenic mouse model.

2011 – 2014 Edgar LeClaire, MD, FPMRS fellow
Mentored in conduct of research, AUGS Benson Grant project.

2012 – 2015 Stephanie Pickett, MD, FPMRS fellow
Mentored in conduct of research, MS thesis in the role of skeletal muscle type in women with different degrees of prolapse. Identification of cytokine profiles in women with different degrees of prolapse.

2013 – 2016 Benjamin Barenberg, MD, FPMRS fellow
Mentored in conduct of research, MS thesis in the role of satellite cells skeletal muscle regeneration in women with different degrees of prolapse.

2014-2017 Daniel Stone, MD, FPMRS fellow

Curriculum Vitae

Mentored in conduct of research, MS thesis in the role of cytokines and macrophages in skeletal muscle regeneration in women with different degrees of prolapse.

2015-2018 Soorena Fatehchehr, MD, FPMRS fellow

VII. Society Memberships

1995-Present (FACOG)	Fellow, American College of Obstetrics and Gynecology
2008-Present	Fellow, American College of Surgeons (FACS) 03135880
2012 – Present	MGMA / ACPME
2011 – Present Gynecology	The International Society of Ultrasound in Obstetrics and
2011 – Present	The American Institute of Ultrasound in Medicine (AIUM)
2008 – Present	The American College of Surgeons (ACS)
2005 – Present	International Continence Society (ICS)
2005 – Present	International Urogynecological Association (IUGA)
1995 – Present	American College of Obstetrics and Gynecology (ACOG)
1994 – Present	American Urogynecological Society (AUGS)

VIII. Committee Memberships

2015- Member of the ICI committee on Imaging and other tests under the chairmanship of Vik Khullar, **6th International Consultation on Incontinence, to be held at the ICS annual meeting in Tokyo, 13th to 14th September 2016**

2015-2018 Development Committee	(IUGA) International Urogynecologic Association Research &
2015 – Current	Society of Gynecologic Surgeons Pelvic Floor Anatomy Group
2015 – Current	Working with AIUM / IUGA Ultrasound Practice Accreditation Council and Clinical Standards Committee to develop joint practice and training parameters for pelvic floor imaging.
2015 – Current	IUGA Imaging SIG, working on various international projects
2015 – Present	PFD Research Foundation Grant Reviewer

Curriculum Vitae

2010 – 2014 Advisory Council (NSAC)	American Federation for Aging Research, National Scientific
2014 - Present	Techniques in Coloproctology, Reviewer
2011 – 2012 Program monitor	The American Urogynecologic Society 2012 Scientific meeting,
2011 – Present	Open Journal of Urology, editorial board member
2010 – Present	ACOG Kenneth Gottsfield-Charles Hohler Memorial Foundation Research Award in Ultrasound Committee member
2008 – 2011 Program Committee	The American Urogynecologic Society Annual Scientific Meeting
2007 – Present	The American Urogynecologic Society, Abstract Reviewer
2007 – Present	AUGS Basic Science Grant Reviewer
2005 – 2008	The American Urogynecologic Society Research Committee
2011 – Present	The British Journal of Obstetrics and Gynecology, Reviewer
2003 – Present	The International Urogyn Pelvic Floor Dysfunction J, Reviewer
2010 – Present	The Journal of Urology, Reviewer
2009 – Present	American Journal of Obstetrics and Gynecology, Reviewer
2006 – Present	Female Pelvic Medicine and Reconstructive Surgery, Reviewer
2006 – Present	Neurourology and Urodynamics, Reviewer

Hospital / Agency:

2015-Present	Staff Physician Inova Fairfax Hospital, Falls Church, VA
2002-15	Staff Physician OU Medical Center, Oklahoma City, OK
2003-15	Courtesy Staff Physician Integris Baptist Medical Center, Oklahoma City, OK

Licensure

1995-2003	Louisiana	Inactive
2002-	Oklahoma	Active/Current
2015	Virginia	Active

Exhibit B

Exhibit B

Clinical Literature Reliance List

Document Date	Title	Primary Author	Publication	Bates Start
	Evaluation and Management of Complications From Synthetic Mesh After Pelvic Reconstructive Surgery: A Multi-Center	Abbot, et al	Presentation Number: Paper 29	
2014-01-01	Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study	Abbott, et al	Am J Obstet Gynecol 2014;210:163.e1-8	
2011-01-01	Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: A Meta-Analysis of Effectiveness and Complications	Abdel-Fattah, et al	European Urology 60 (2011) 468 - 480	
2006-01-01	How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape	Abdel-Fattah, et al	BJU Int, 98(3), 594-598	
2008-01-01	Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse	Abdel-Fattah, et al	BJOG 2008;115:22–30	
	A RANDOMISED PROSPECTIVE SINGLE-BLINDED STUDY COMPARING "INSIDE-OUT" VERSUS "OUTSIDE-IN" TRANSOBTURATOR TAPES IN THE MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE (E-TOT STUDY); 3 YEARS FOLLOW-UP.	Abdel-fattah, et al	Poster 18	
2010-01-01	Evaluation of transobturator tapes (E-TOT) study: randomised prospective single-blinded study comparing inside-out vs. outside-in transobturator tapes in management of urodynamic stress incontinence: Short term	Abdel-fattah, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 149 (2010) 106-111	
2010-04-12	Randomised prospective single-blinded study comparing 'inside-out' versus 'outside-in' transobturator tapes in the management of urodynamic stress incontinence: 1-year outcomes from the E-TOT study	Abdel-fattah, et al	BJOG 2010;117:870—878	

Clinical Literature Reliance List

2010-05-18	Tension-Free Vaginal Tape versus Secure Tension-Free Vaginal Tape in Treatment of Female Stress Urinary Incontinence	Abdelwahab, et al	Current Urology, 4(2), 93-98	
2011-01-01	Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials; a systematic review	Abed, et al	Int Urogynecol J (2011) 22:789–798	
	FDA Literature Chart	Abed, Husam		
2011-01-01	Treatment of moderate to severe female stress urinary incontinence with the adjustable continence therapy (ACT) device after failed surgical repair	Aboseif, et al	World J Urol (2011) 29:249—253	
	Is Tissue Engineering and Biomaterials the Future for Lower Urinary Tract Dysfunction (LUTD)/Pelvic Organ Prolapse (POP)?	Aboushwareb, et al		
2009-01-01	Tissue mechanics, animal models, and pelvic organ prolapse: A review	Abramowitch, et al	European Journal of Obstetrics & Gynecology and	
2011-01-01	Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe	Abrams, et al	European Urology 60:1207-1211	
1997-01-01	Kinetic study of the thermal oxidation of polypropylene	Achimsky, et al	Polymer Degradation and Stability 57 (1997) 231-240	
2006-12-01	ACOG Committee Opinion Number 352: Innovative Practice: Ethical Guidelines	ACOG	ACOG Committee Opinion No. 352	
2007-02-01	ACOG PRACTICE BULLETIN NUMBER 79: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN-GYNECOLOGISTS	ACOG	The American College of Obstetrics & Gynecology	
2007-09-01	ACOG PRACTICE BULLETIN NUMBER 85: CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN -GYNECOLOGISTS NUMBER 85	ACOG	The American College of Obstetricians and Gynecologists	
2005-06-01	ACOG Practice Bulletin Number 63: Clinical Management Guidelines for Obstetrician-Gynecologists	Acog Committee on Practice Bulletins--Gynecology	Obstet Gynecol	
2008-10-01	A Randomized Comparison of Two Synthetic Mid-Urethral Tension-Free Slings	Agarwala N	UroToday International Journal / Vol 1 / Iss 4/	

Clinical Literature Reliance List

2007-01-01	Laparoscopic sacral colpopexy with Gynemesh as graft material-Experience and	Agarwala, et al	Journal of Minimally Invasive Gynecology (2007) 14, 577-583	
2014-01-01	Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence	Agnew, et al	Int Urogynecol J (2014) 25:235-239	
2011-01-01	Long term patient satisfaction after suburethral sling operation for stress	Al-Omary, Atalla	Int Urogynecol J (2011) 22 (Suppl 3):	
2007-01-01	Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence	Albo, et al	N Engl J Med 2007;356:2143-55	
2012-12-01	Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24	Albo, et al	J Urol Vol. 188, 2281-2287	
	Isolation of fibroblasts for coating of meshes for reconstructive surgery: differences between mesh types	Albrich, et al		
2003-01-02	Use of Cadaveric Fascia Lata To Correct Grade IV Cystocele	Almeida, et al	International Braz J Urol Vol. 29 (1): 48-52	
2011-01-01	Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse	Altman, et al	N Engl J Med 2011;364:1826-36	
2007-02-01	Perioperative Morbidity Using Transvaginal Mesh in Pelvic Organ Prolapse Repair	Altman, et al	Obstet Gynecol 2007;109:303-8	
	INTRA- AND PERIOPERATIVE MORBIDITY FOLLOWING PELVIC ORGAN PROLAPSE REPAIR USING A TRANSVAGINAL SUTURE CAPTURING MESH DEVICE COMPARED TO TROCAR GUIDED TRANSVAGINAL MESH AND TRADITIONAL COLPORRHAPHY	Altman, et al	Abstract	
2007-01-01	Lower urinary tract injuries associated with the out-in transobturator tape - is cystoscopy required An Argentinean multicenter	Altuna, et al	Int Urogynecol J (2007) 18 (Suppl 1):	
2009-01-01	Clinical and Quality-of-Life Outcomes after Autologous Fascial Sling and Tension-Free Vaginal Tape: A Prospective Randomized Trial	Amaro, et al	International Braz J Urol Vol. 35 (1):60-67	

Clinical Literature Reliance List

1997-01-01	Classification of biomaterials and their related complications in abdominal wall	Amid PK	Hernia (1997) 1:15-21	
2010-01-01	Complications of polypropylene mesh in prolapse surgery	Ammembal, Radley	OBSTETRICS, GYNAECOLOGY AND REPRODUCTIVE MEDICINE	
1998-01-01	Concise review of mechanisms of bacterial adhesion to biomaterial surfaces	An, Friedman	J Biomed Mater Res (Appl Biomater) 43: 338—348	
2008-01-01	Foreign Body Reaction to Biomaterials	Anderson, et al	SEMIN. IMMUNOL. 20(2): 86-	
1985-01-01	Utilization of Adipose Tissue Biopsy in Characterizing Human Halogenated Hydrocarbon Exposure	Anderson, HA	Environmental Health Perspectives	
2007-01-01	Prospective Clinical Trial Comparing Obtape and DUPS to TVT: One-Year Safety and	Andonian, et al	European Urology 52 (2007) 245-252	
2005-01-13	Randomized Clinical Trial Comparing Suprapubic Arch Sling (SPARC) and Tension-free Vaginal Tape (TVT): One-Year Results	Andonian, et al	European Urology 47 (2005) 537—541	
2007-01-01	Complications of Sling Surgery Among Female Medicare Beneficiaries	Anger, et al	Obstet Gynecol 2007;109:707—14	
2010-01-01	Tension-Free Vaginal Tape Versus Transobturator Suburethral Tape: Five-Year Follow-up Results of a Prospective,	Angioli, et al	European Urology 58 (2010) 671-677	
2009-01-01	Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence	Aniulienė R	Medicina (Kaunas) 2009; 45(8)	
1986-03-22	Epistemology of Surgery	Anon	The Lancet	
2009-01-01	The influence of BMI, smoking, and age on vaginal erosions after synthetic mesh repair of pelvic organ prolapses. A multicenter study	Araco, et al	Acta Obstetrica et Gynecologica. 2009; 88: 772—780	
2008-01-24	TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress	Araco, F. et al	Int Urogynecol J (2008) 19:917—926	
2012-01-01	Complications from the Placement of a Tension-Free Suburethral Sling Using the Transobturator and Retropubic Methods for Treatment of Female Urinary Incontinence	Arrabal-Polo, et al	Urologia Internationalis	

Clinical Literature Reliance List

2003-01-01	Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire-based study	Arunkalaivanan, Barrington	Int Urogynecol J (2003) 14: 17—23	
	SINGLE-INCISION MIDURETHRAL TAPE (OPHIRA) VS TRANSOBTURATOR TAPE (OBTRYX): PROSPECTIVE COMPARATIVE	Arunkalaivanan, et al	Abstract 245	
2009-01-01	Efficacy and safety of transobturator tape (Obtryx) in women with stress urinary incontinence and intrinsic sphincter	Arunkalaivanan, et al	Presentation 778	
	Haemorrhage and nerve damage as complications of TVT-O procedure: case report and literature review	Atassi, et al	Arch Gynecol Obstet, 277(2), 161-164	
2013-01-01	Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: Why do tapes fail?	Athanasίου, et al	Int Urogynecol J	
2009-01-01	MIXED URODYNAMIC INCONTINENCE: TVT or TVT-O?	Athansiou, et al	Int Urogynecol J (2009) 20 (Suppl 2):S73–S239	
2011-11-01	AUA Position Statement on the Use of Vaginal Mesh For the Repair of Pelvic Organ Prolapse	AUA	American Urological Association	
2012-04-01	ADULT URODYNAMICS: AUA/SUFU	AUA		
2009-01-01	Guideline for the Surgical Management of Female Stress Urinary Incontinence 2009	AUA		
2011-11-01	AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence	AUA		
2013-01-01	Guidelines for Privileging and Credentialing Physicians for Sacrocolpopexy for Pelvic Organ Prolapse	AUGS	Female Pelvic Medicine & Reconstructive Surgery, 19, 2	
2011-07-01	AUGS Response FDA Safety Communications	AUGS	American Urogynecologic	
	Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders	AUGS	American Urogynecologic Society	
2011-09-09	AUGS statement September 8-9, 2011	AUGS	AUGS	

Clinical Literature Reliance List

2012-01-01	Guidelines for Providing Privileges and Credentials to Physicians for Transvaginal Placement of Surgical Mesh for Pelvic Organ	AUGS	Female Pelvic Medicine & Reconstructive Surgery Volume 18, Number 4	
2014-01-01	Committee Opinion: Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment	AUGS and ACOG	Female Pelvic Medicine & Reconstructive Surgery 20; 5: 248 - 251	
	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	AUGS, SUFU		
2014-01-03	Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence	AUGS-SUFU		
2009-01-01	Do novo stress incontinence and pelvic muscle symptoms after transvaginal mesh	Aungst, et al	Am J Obstet Gynecol 2009;201:73.e1-7	
2006-01-01	Vaginal erosion, sinus formation, and ischiorectal abscess following transobturator tape: ObTape implantation	Babalola, et al	Int Urogynecol J (2006) 17: 418—421	
2008-01-01	Prosthetic Material in Ventral Hernia Repair: How Do I Choose?	Bachman, Ramshaw	Surg Clin N Am 88 (2008) 101–	
2005-10-01	Severe Mesh Complications Following Intravaginal Slingplasty	Baessler, et al	Obstet Gynecol 2005;106:713–6)	
2006-01-01	Mesh augmentation during pelvic-floor reconstructive surgery: risks and benefits	Baessler, Maher	Curr Opin Obstet Gynecol 18:560–566	
2006-01-01	Principles of Polymer Science, 2nd Edition	Bahadur, Sastry		
2009-01-01	Review of synthetic mesh-related complications in pelvic floor reconstructive	Bako, Dhar	Int Urogynecol J (2009) 20:103-111	
	LONG-TERM 6 YEAR PATIENT SATISFACTION AND QUALITY OF LIFE OUTCOMES AFTER AN ADVANTAGE SLINGS FOR STRESS URINARY INCONTINENCE	Balachandran, Duckett	Abstract	
2008-08-01	Prospective evaluation of the safety and efficacy of the Apogee system for treatment of vault prolapse	Balakrishnan, et al	Journal of Obstetrics and Gynaecology; 28(6): 618–620	
	PROSPECTIVE MULTICENTRE OBSERVATIONAL TRIAL OF COMPOSITE POLYGLACTIN/POLYPROPYLENE MESH (VYPRO* MESH) FOR RECONSTRUCTION OF RECURRENT ANTERIOR VAGINAL WALL	Balmforth, Cardozo	Poster	

Clinical Literature Reliance List

2011-01-01	Comparison of transobturator tape (TOT) vs Burch method in treatment of stress urinary incontinence	Bandarian, et al	Journal of Obstetrics and Gynaecology, August 2011;31:518-520	
2006-01-01	Abscess formation following trans-obturator tape procedures	Banks, et al	Int Urogynecol J (2006) 17 (Suppl.. 2):	
2005-12-01	Contemporary views on female pelvic anatomy	Barber M	Cleveland Clinic Journal of Medicine VOLUME 72	
2013-01-01	Surgical Techniques for Removing Problematic Mesh	Barber M	CLINICAL OBSTETRICS AND GYNECOLOGY Volume 56,	
2006-01-01	Perioperative complications and adverse events of the MONARC transobturator tape, compared with the tension-free vaginal tape	Barber, et al	American Journal of Obstetrics and Gynecology (2006) 195, 1820–5	
2012-01-01	Single-Incision Mini-Sling Compared With Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial	Barber, et al	Obstet Gynecol 2012;119:328–37)	
2008-00-00	Risk factors associated with failure 1 year after retropubic or transobturator	Barber, et al	Am J Obstet Gynecol 199, 666 e1-7	
2008-03-00	Transobturator Tape Compared With Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized	Barber, et al	Obstet Gynecol 2008;111:611--21	
2000-01-01	Bilateral uterosacral ligament vaginal vault suspension with site-specific endopelvic fascia defect repair for treatment of pelvic organ prolapse	Barber, et al	Am J Obstet Gynecol 2000;183:1402-11	
2009-01-01	Defining Success After Surgery for Pelvic Organ Prolapse	Barber, et al	Obstet Gynecol 2009;114:600–9	
1997-01-01	Intraligamentous Nerves as a Potential Source of Pain After Sacrospinous Ligament Fixation of the Vaginal Apex	Barksdale, et al	Int Urogynecol J 8:121-125	
2015-02-28	the impact of boundary conditions of surface curvature of polypropylene mehs in response to uniaxial loading	Barone, et al	Journal of Biomechanics	

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2008-01-01	A multi-centre, randomised clinical control trial comparing the retropubic (RP) approach versus the transobturator approach (TO) for tension-free, suburethral sling treatment of urodynamic stress incontinence: the TORP	Barry, et al	Int Urogynecol J (2008) 19:171—178	
2014-01-01	Management of Mesh Complications after SUI and POP Repair: Review and Analysis of the Current Literature	Barski and Deng	BioMed Research International	
2012-07-21	Transvaginal Profit mesh surgery due to advanced pelvic organ prolapse does not impair female sexual function:a prospective	Bartuzi, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 165	
2013-01-01	Three-year results from a randomised trial of a retropubic mid-urethral sling versus the Miniarc single incision sling for stress urinary	Basu, Duckett	Int Urogynecol J	
2010-01-01	A randomised trial of a retropubic tension-free vaginal tape versus a mini-sling for stress incontinence	Basu, Duckett,	BJOG 2010;117:730—735	
	Pain and Functional Impairment 1 Year After Inguinal Herniorrhaphy: A Nationwide Questionnaire Study	Bay-Nielsen, et al	ANNALS OF SURGERY Vol. 233, No. 1, 1-7	
2007-01-01	Polypropylene midurethral tapes do not have similar biologic and biomechanical performance in the rat	Bazi, et al	European Urology 51 (2007) 1364-1375	
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2003-01-01	Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A	Bekelman, et al	JAMA. 2003;289:454-465	
2011-01-08	The design of an industry-sponsored randomized controlled trial to compare synthetic mesh versus biologic mesh for	Bellows, et al	Hernia (2011) 15:325—332	
2012-07-03	Pelvic organ prolapse transvaginal repair by the Prolift system: Evaluation of efficacy and complications after a 4.5 years follow up	Benbouzid, et al	International Journal of Urology (2012) 19, 1010–1016	
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1998-12-01	Complications of Groin Hernia Surgery	Bendavid R	GROIN HERNIA SURGERY	

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2014-07-01	Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain	Bendavid, et al	International Journal of Clinical Medicine. 2014; 5:799-810	
2015-11-23	A mechanism of mesh-related post-herniorrhaphy neuralgia	Bendavid R, et al	Hernia. 2015 Nov 23. [Epub ahead of print]	
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2005-01-20	Pudendal neuralgia, a severe pain syndrome	Benson, Griffis	American Journal of Obstetrics and Gynecology (2005) 192,	
1995-01-01	Three surgical procedures for genuine stress incontinence: Five-year follow-up of a prospective randomized study	Bergman, A; Elia, G	Am J Obstet Gynecol	
2005-01-01	The Pains of Endometriosis	Berkley, et al	Science 308, 1587	
2004-11-01	Conceptual advances in the surgical management of genital prolapse	Berrocal, et al	J Gynecol Obstet Biol Reprod 2004; 33:577-587	
	Rising awareness of the complications of synthetic slings	Bhargava,Chapple		
2001-01-01	Trocar injuries in laparoscopic surgery	Bhojrul, et al	J Am Coll Surg	
2011-01-01	RANDOMISED TRIAL OF TVT-O AND TVT-S FOR THE TREATMENT OF STRESS URINARY	Bianchi, et al	Int Urogynecol J (2011) 22 (Suppl 1):S1–S195	
2000-01-01	Sling techniques in the treatment of genuine stress incontinence	Bidmead, Cardozo	BJOG 2000, 107(2), pp. 147-156	
2010-01-01	The DSM Diagnostic Criteria for Dyspareunia	Binak V	Arch Sex Behav (2010)	
	Demands and properties of alloplastic implants for the treatment of stress urinary	Binneboesel, et al		
2011-01-12	Biocompatibility of prosthetic meshes in abdominal surgery	Binnebosel, et al	Semin Immunopathol (2011) 33:235–243	
2002-01-01	The role of synthetic and biological prostheses in reconstructive pelvic floor surgery	Birch, Fynes	Curr Opin Obstet Gynecol 14:527-535	
2013-04-19	Mesh cancer: long-term mesh infection leading to squamous-cell carcinoma of the	Birolini, et al	Hernia	
2004-01-01	Urethral reconstruction after erosion of slings in women	Blaivas and Sandhu	Current Opinion in Urology 2004, 14:335–338	

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2011-01-01	Pubovaginal Fascial Sling for the Treatment of all Types of Stress Urinary Incontinence: Surgical Technique and Long-term Outcome	Blaivas, Chaikin	Urol Clin N Am	
2013-10-01	Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications	Blaivas, et al	J Urol Vol. 190, 1281-1286	
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	Short term complications of the tension free vaginal tape operation for stress urinary incontinence in women	Bodelsson, et al		
2009-01-01	Pelvic nerve injury following gynecologic surgery: a prospective cohort study	Bohrer, et al	Am J Obstet Gynecol 2009;201:531.e1-7	
2013-06-01	Adherence to Behavioral Interventions for Stress Incontinence: Rates, Barriers, and	Borello-France, et al	Physical Therapy 93, 6:757-773	
2009-01-01	Arcus-anchored acellular dermal graft compared to anterior colporrhaphy for stage II cystoceles and beyond	Botros, et al	Int Urogynecol J	
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2010-01-01	Postoperative Neuropathy in Gynecologic	Bradshaw, Advincula	Obstet Gynecol Clin N Am 37	
2010-01-01	Anterior Vaginal wall Prolapse: Assessment and Treatment	Brincat, et al	CLINICAL OBSTETRICS AND GYNECOLOGY Volume 53,	
2010-01-01	Hernia repair: the search for ideal meshes	Bringman, et al	Hernia (2010) 14:81—87	
	SYNTHETIC VAGINAL TAPES FOR STRESS INCONTINENCE	British Association of Urological Surgeons		
2011-07-01	Comparison of the outcomes of the sling technique using a commercial and hand-made polypropylene sling	Brito, et al	International Braz J Urol Vol 37 (4): 519-527	
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2012-09-07	HIGH NUMBER OF COMPLICATIONS FOLLOWING INSERTION OF THE PINNACLE PELVIC FLOOR REPAIR KIT: A CAUSE FOR	Brouard, Jeffery	Presentation Abstract	
2013-01-01	Long-term follow-up of porcine dermis pubovaginal slings	Broussard, et al	Int Urogynecol J (2013) 24:583—587	
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2000-11-01	CADAVERIC VERSUS AUTOLOGOUS FASCIA LATA FOR THE PUBOVAGINAL SLING: SURGICAL OUTCOME AND PATIENT	Brown, Govier	J Urol 164:1633-1637	
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	Collagen-coated polypropylene mesh in vaginal prolapse surgery: an observational	Cervigni, et al	European Journal of Obstetrics & Gynecology and	
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2014-01-01	MESH REMOVAL FOLLOWING SLING-MESH PLACEMENT: A MULTICENTER STUDY	Chinthakanan, et al	Int Urogynecol J (2014) 25 (Suppl 1):S1—S240	
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2011-12-09	Anatomic and Functional Outcomes with the Prolift Procedure in Elderly Women with Advanced Pelvic Organ Prolapse Who Desire Uterine Preservation	Cho, et al	Journal of Minimally Invasive Gynecology, Vol 19, No 3	
2001-07-01	GENETIC MATERIAL IS PRESENT IN CADAVERIC DERMIS AND CADAVERIC FASCIA	Choe, Bell	J Urol 166, 122-124	
2012-01-01	Use of Mesh During Ventral Hernia Repair in Clean-Contaminated and Contaminated Cases	Choi, et al	Ann Surg 2012;255:176—180	
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2012-01-01	TRANSLABIAL ULTRASOUND FOR LOCALIZATION OF VAGINAL MESH	Chow, Raz	Presentation Number: Poster 127	
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1985-03-05	Characterization of morphologic and mechanical properties of surgical mesh	Chu, Welch	Journal of Biomedical Materials Research, Vol. 19, 903-916	
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2002-01-01	Trust in Medicine	Clark C	Journal of Medicine and	
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2010-01-06	Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of	Clave, et al	Int Urogynecol J (2010) 21:261–	
2006-01-01	Textile Analysis of Heavy Weight, Mid-	Cobb, et al	Journal of Surgical Research 136, 1–7	
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	Biomaterials and the Evolution of Hernia Repair I: The History of Biomaterials and the Permanent Meshes	Cortes, et al		
2009-09-02	Anatomy of Pelvic Floor Dysfunction	Corton M	Obstet Gynecol Clin N Am 36	
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2013-01-01	Surgical management of female SUI: is there a gold standard?	Cox, et al	Nat. Rev. Urol.	
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		An overview of tissue and whole organ decellularization processes	Crapo, et al	
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2008-01-01	Complications of Mid Urethral Slings: Important Outcomes for Future Clinical Trials	Daneshgari, et al	J Urol Vol. 180, 1890-1897	
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2003-12-05	Sacro-spinous ligament fixation peri- operative complications in 195 cases:visual approach versus digital approach of the sacro-	David-Montefiore, et al	European Journal of Obstetrics & Gynecology and Reproductive Biology 116	
2006-05-12	Introduction to the 2005 IUGA Grafts	Davila GW	International Urogynecology	
	Multicenter experience with the Monarc transobturator sling system to treat stress urinary incontinence	Davila, et al		
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2002-01-01	Pelvic Floor Dysfunction Management Practice Patterns: A Survey of Members of the International Urogynecological	Davila, et al	Int Urogynecol J (2002) 13:319–325	
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1988-01-01	Polymer Stabilizers. A Survey with Reference to Possible Applications in the Conservation Field	de la Rie ER	STUDIES IN CONSERVATION. 33: 9-22	
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2009-11-19	Bilateral anterior sacrospinous ligament suspension associated with a paravaginal repair with mesh : short-term clinical results of a pilot study	de Tayrac, et al	Int Urogynecol J (2010) 21:293298	BSCM06300019395
2007-01-01	Collagen-coated vs noncoated low-weight polypropylene meshes in a sheep model for vaginal surgery. A pilot study.	de Tayrac, et al	Int Urogynecol J Pelvic Floor Dysfunct, 18(5), 513-520	
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	Anatomical and functional assessment of prolapse repair by vaginal route using a collagen coating polypropylene mesh. A french prospective multicentre study, 3-year	de Tayrac, et al	IUGA 2008	
2006-01-01	Long-term anatomical and functional assessment of trans-vaginal cystocele repair using a tension-free polypropylene mesh	de Tayrac, et al	Int Urogynecol J (2006) 17: 483-488	
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2002-01-01	Safety and Efficacy of Sacrospinous Vault Suspension	Lovatsis, Drutz	Int Urogynecol J (2002) 13:308–313	
2013-01-01	Colpocleisis: Current Practice and Complications	Lowenstein, Erisson	Complications of Female Incontinence and Pelvic	
2006-01-27	Neural pain after uterosacral ligament vaginal suspension	Lowenstein, et al	Int Urogynecol J (2007) 18: 109–110	

	Small-pore polypropylene slings: still out	Lowery, et al		
2012-01-01	EAU Guidelines on Surgical Treatment of Urinary Incontinence	Lucas, et al	European Urology 62 (2012) 1118—1129	
2005-01-01	Suture erosion and wound dehiscence with permanent versus absorbable suture in reconstructive posterior vaginal surgery	Luck, et al	Am J Obstet Gynecol	
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2009-01-01	Polypropylene mesh vs. site-specific repair in the treatment of anterior vaginal wall prolapse: preliminary results of a randomized	Lundardelli, et al	Rev. Col. Bras. Cir. 2009; 36(3): 210-216	
2011-05-16	COMPARISON OF OUTCOMES BETWEEN DIFFERENT SUB-URETHRAL SLING PROCEDURES FOR FEMALE STRESS URINARY INCONTINENCE: ANALYSIS FROM A HOSPITAL	Magee, et al	J Urol 185; 4S; e407	BSCM 12800021793
2012-01-01	A Real-World Comparative Assessment of Complications Following Various Mid-Urethral Sling Procedures for the Treatment of Stress Urinary Incontinence	Magee, et al	Journal of Long-Term Effects of Medical Implants, 22(4): 329-340	

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2006-01-01	Surgical management of anterior vaginal wall prolapse an evidencebased literature review	Maher, Baessler	Int Urogynecol J (2006) 17: 195–201	
2010-01-01	Surgical management of pelvic organ prolapse in women review	Maher, et al	The Cochrane Library 2010, Issue 8	
2011-04-01	Laparoscopic sacral colpopexy versus total vaginal mesh for vaginal vault prolapse: a	Maher, et al	Am J Obstet Gynecol 2011;204:360.e1-7	
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2013-09-01	The transvaginal mesh decade	Maher, Haya	Expert Review of Obstetrics & Gynecology. 8.5 (Sept. 2013): p	
1993-01-01	Migration of bacteria along synthetic polymeric fibers	Mahmoud, et al	J. Biomater. Sci. Polymer Edn, Vol. 4, No. 6, pp. 567-578	
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2011-01-01	Correlation between shrinkage and infection of implanted synthetic meshes using an	Mamy, et al	Int Urogynecol J (2011) 22:47–	
2012-10-10	Graft-related complications and biaxial tensiometry following experimental vaginal implantation of flat mesh of variable	Manodoro, et al	BJOG 2013;120:244–250	
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2008-12-01	Complications requiring reoperation following vaginal mesh kit procedures for	Margulies, et al	Am J Obstet Gynecol 2008;199:678.e1-678.e4	

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2014-01-01	A porous tissue engineering scaffold selectively degraded by cell-generated reactive oxygen species	Martin, et al	Biomaterials 35 (2014)	
	The Micorbiota of the Vagina and Its Influence on Women's Health and Disease	Martin DH		
1998-01-01	Comparison of the In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery	Mary, et al	ASAIO J. 44: 199-206	
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2006-01-01	Systemic allergic reaction to polypropylene mesh used in surgical treatment of cystocele. A case report	Matyszewski, et al	Menopause Review 2006; 4:239-243	
2012-01-01	Outcome of Obtryx transobturator sling for stress incontinence in Scottish women	May, et al	Poster 429	
2015-03-24	Mechanical biocompatibility of highly deformable biomedical materials	Mazza, E; Ehret, AE	Journal of the Mechanical Behavior of Biomedical	
2012-01-01	Development of polylactide and polyethylene vinyl acetate blends for the manufacture of vaginal rings	Mc Conville, et al	J Biomed Mater Res B Appl Biomater, 100(4), 891-895	
2010-01-01	An update on surgery for pelvic organ	McIntyre, et al	Curr Opin Urol 20:490–494	
1981-01-01	From "Promising Report" to "Standard Procedure": Seven Stages in the Career of a	McKinlay J	Seven Stages in the Career of a Medical Innovation	
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	Late urethral erosion of transobturator suburethral mesh (Obtape): a minimally invasive management under local anaesthesia	Mendonca, et al		
2011-12-01	Colporrhaphy Compared With Mesh or Graft-Reinforced Vaginal Paravaginal Repair for Anterior Vaginal Wall Prolapse	Menefee, et al	Obstet Gynecol 2011;118:1337–44	

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1991-01-01	Factors Influencing Bacterial Adherence to Biomaterials	Merritt, Chang	BiomatAppl 1991; 5:185	
2007-03-08	Peri-operative morbidity and early results of a randomised trial comparing TVT and TVT-0	Meschia, et al	Int Urogynecol J (2007) 18:1257—1261	
2007-01-01	Porcine Skin Collagen Implants to Prevent Anterior Vaginal Wall Prolapse Recurrence: A Multicenter, Randomized Study	Meschia, et al	J Urol Vol. 177, 192-195	
	In vivo and in vitro degradation of monofilament absorbable sutures, PDS and	Metz, et al	Biomaterials, 11(1), 41-45	
2006-01-01	Hydrogen peroxide producing lactobacilli in women with vaginal infections	Mijac, et al	European Journal of Obstetrics & Gynecology and	
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2005-01-01	Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh	Milani, et al	BJOG Vol. 112, pp. 107-111	
2011-01-01	Sexual Function Following Trocar-guided Mesh or Vaginal Native Tissue Repair in Recurrent Prolapse: A Randomized Controlled	Milani, et al	J Sex Med 2011;8:2944–2953	
2009-01-01	International Urogynecological Association-Short Term Outcomes and Peri-Operative Events after a new transvaginal anterior and	Miller D	International Urogynecological Association	
	Prospective Clinical Assessment of the Transvaginal Mesh Technique for Treatment of Pelvic Organ Prolapse—5-Year Results	Miller, et al	AUG S CONFERENCE PRESENTATION	
	Informed surgical consent for a mesh/graft-augmented vaginal repair of pelvic organ	Miller, et al	Int Urogynecol J	BSCM04400014002

2009-01-01	COMPARISON OF TRANSVAGINAL ANTERIOR MESH SYSTEMS FOR SUPPORT OF ANTERIOR AND APICAL COMPARTMENTS IN A CADAVER	Miller, Lotze	Abstract	
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2009-05-00	Surgical Resection for Suburethral Sling Complications After Treatment for Stress Urinary Incontinence	Misrai, et al	J Urol 181, 2198-2203	
2007-04-21	Rising use of synthetic mesh in transvaginal pelvic reconstructive surgery: A review of the risk of vaginal erosion	Mistrangelo, et al	Journal of Minimally Invasive Gynecology (2007) 14, 564–569	
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	FEASIBILITY AND SHORT-TERM OUTCOMES FOLLOWING THE USE OF THE UPHOLD VAGINAL SUPPORT SYSTEM FOR TREATMENT OF SYMPTOMATIC VAGINAL PROLAPSE	Mobley, et al	Neurourology and Urodynamics DOI 10.1002	
2011-01-01	Painful Love - "Hispareunia" after Sling Erosion of the Female Partner	Mohr,et al	J Sex Med 8:1740–1746	
	Carcinogenesis Induced by Foreign Bodies	Moizhes T.G.		
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2010-09-01	Vaginal Mesh Kits for Prolapse 2010: Update in Technology and Techniques to Minimize Complications	Moore, Davila	The Female Patient VOL 35	

2011-08-25	Single-incision vaginal approach to treat cystocele and vault prolapse with an anterior wall mesh anchored apically to the	Moore, et al	Int Urogynecol J (2012) 23:85–91	
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	Tension-free vaginal tape for primary genuine stress incontinence: a two-centre follow-up	Moran, et al		

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2007-01-18	Vaginal pressure during daily activities before and after vaginal repair	Mouritsen, et al	Int Urogynecol J (2007) 18:943–948	
	Cystocele repair by vaginal route: comparison of three different surgical techniques of mesh placement	Mourtialon, et al		
2010-01-01	Use of vaginal mesh in the face of recent FDA warnings and litigation	Mucowski, et al	Am J Obstet Gynecol 2010;203:103.e1-4	

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2008-00-00	New Objective Measurement to Characterize the Porosity of Textile Implants	Muhl, et al	J Biomed Mater Res B Appl Biomater, 84(1), 176-183	
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2010-01-01	Urethral strictures	Mundy, Andrich	BJUI	
	Clinical Practice Guidelines on Vaginal Graft Use From the Society of Gynecologic	Murphy M		
	Use of Mesh and Materials in Pelvic Floor	Murphy M	Obstet Gynecol Clin N Am 36	
2012-00-00	Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: "Update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ	Murphy, et al	Int Urogynecol J (2012) 23:5–9	
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2011-01-01	Mesh kits for anterior vaginal prolapse are not cost effective	Murray, et al	Int Urogynecol J (2011) 22:447–452	
2011-04-00	Urethral Distortion After Placement of Synthetic Mid Urethral Sling	Murray, et al	J Urol 185, 1321-1326	
2007-02-20	Bladder erosion of tension-free vaginal tape presented as vesical stone; management and review of literature	Mustafa, Wadie	Int Urol Nephrol (2007) 39:453-455	
	Stress urinary incontinence in women Transobturator midurethral slings	Nager		
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	Pelvic floor reconstructive surgery: which aspects remain controversial?	Natale, Franca		
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2008-06-01	Surgical repair of vaginal wall prolapse using mesh	National Institute for Health and Clinical	National Institute for Health and Clinical Excellence	
2008-00-00	Outcome After Anterior Vaginal prolapse repair: A Randomized Controlled Trial	Nguyen, Burchette	Obstet Gynecol 2008;111:891–8	
2012-03-01	Perioperative Complications and reoperations after incontinence and prolapse surgeries using prosthetic implants	Nguyen, et al	Obstet Gynecol 2012;119:539–46	
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2013-01-01	Additional Written Evidence	NICE		
	A New Operation for Genitourinary Prolapse	Nicita G		
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2015-04-01	Creating a gold standard surgical procedure: the development and implementation of TVT	Nilsson, CG	Int Urogynecol J. 2015 Apr; 26(4):467-9.	
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	Complications of midurethral slings and their management	Nitti V		

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	Urinary incontinence in women	Norton, Brubaker		
2010-01-01	Updated Systematic Review and Meta-Analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence	Novara, et al	EUROPEAN UROLOGY 58 (2010)218–238	
2006-01-01	Critical Assessment of Pelvic Floor Surgical Reconstruction Outcome	Novara, et al	eau-ebu update series 4 (2006) 202–213	
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2007-02-28	Marketed vaginal mesh kits: rampant experimentation or improved quality of care	Nygaard I	Int Urogynecol J (2007) 18:483–484	

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2013-05-15	Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse	Nygaard, et al	JAMA. 2013;309(19):2016-2024	
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	A three-incision approach to treat persistent vaginal exposure and sinus tract formation related to ObTape mesh insertion	Occhino, et al		
	Do You Believe in Magic? The Sense and Nonsense of Alternative Medicine	Offitt PA		
2011-01-01	Minimally Invasive Synthetic Suburethral Sling Operations for Stress Urinary Incontinence in Women: A Short Version Cochrane Review	Ogah, et al	Neurourology and Urodynamics 30:284–291 (2011)	
2009-01-01	Minimally Invasive synthetic suburethral sling operations for stress urinary incontinence in women (Review)	Ogah, et al	The Cochrane Library	
2011-01-01	Exploratory Study Assessing Efficacy and Complications of TVT-O, TVT-Secur, and Mini-Arc: Results at 12-Month Follow-Up	Oliveira, et al	European Urology 59 (2011) 940-944	
2007-01-01	COMPARISON OF RETRO-PUBIC TVT, PRE-PUBIC TVT AND TVT TRANSOBTURATOR IN SURGICAL TREATMENT OF WOMEN WITH STRESS URINARY INCONTINENCE	Oliveira, et al	Int Urogynecol J (2007) 18 (Suppl 1):S107–S244	
1996-12-02	Epidemiology of Surgically Managed Pelvic Organ Prolapse and Urinary Incontinence	Olsen, et al	Obstet Gynecol 1997;89:501-6	
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2010-10-01	Polypropylene Vaginal Mesh Grafts in	Ostergard D	OBSTETRICS & GYNECOLOGY	
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2013-01-01	Long-term follow-up after native tissue repair for pelvic organ prolapse	Oversand, et al	Int Urogynecol J	
	Porous acellular porcine dermal collagen implants to repair fascial defects in a rat model: biomechanical evaluation up to 180	Ozog, et al		

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2010-05-04	A randomized trial comparing tension-free vaginal tape with tension-free vaginal tape-obturator: 36-month results	Palva, et al	Int Urogynecol J (2010) 21:1049–1055	
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	Evolution of Midurethral and Other Mesh Slings- a Critical Analysis	Petros, Papadimitriou		
2015-06-01	The Significant Morbidity of Removing Pelvic Mesh From Multiple Vaginal Compartments	Pickett, et al	Obstetrics & Gynecology	
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	Evaluating the porcine dermis graft InteXen in three-compartment transvaginal pelvic organ prolapse repair	Ramanah, et al		
2008-01-01	Prospective Study of the Perigee System for the Management of Cystoceles-medium-term Follow up	Rane A	Ausr N I J Obstet Gynaecol. 2008; 48:427-32	
2009-01-01	Outcomes Following Mid-Urethral Sling Placement in Patients with Intrinsic Sphincteric Deficiency: Monarc Slings	Rapp, et al	International Braz J Urol Vol. 35 (1): 68-75	
	Recurrent Thigh Abscess with Necrotizing Fasciitis from a Retained Transobturator Sling	Rardin, et al		
2009-01-08	New Considerations in the Use of Vaginal Mesh for Prolapse Repair	Rardin, Washington	Journal of Minimally Invasive Gynecology (2009) 16,	
	Traditional suburethral sling operations for urinary incontinence in women (Review)	Rehman, et al		
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	Long-term 5-Year Followup of the Results of the Vesica Procedure	Reid, Parys		
2011-08-01	A series of Advantage suburethral slings	Renganathan, et al	Journal of Obstetrics and Gynaecology, August 2011 ; 31	
2011-01-01	Mid-Term Follow-up of a Randomized Trial Comparing TVT-O, TVT-Secur and Mini-Arc	Resende, et al	Eur Urol Suppl 2011;10(2):244	
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2012-05-01	Obturator Foramen Dissection for Excision of Symptomatic Transobturator Mesh	Reynolds, et al	J Urol 187:1680-1684	
2011-01-01	Treatment of Recurrent Vaginal Prolapse with the Pinnacle Pelvic Floor Repair Kit	Ricci, et al	Int Urogynecol I (2011) 22 (Suppl I):S I-S195	
2010-06-03	Retropubic Versus Transobturator Midurethral Slings for Stress Incontinence	Richter, et al	n engl j med 362;22	
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2008-01-01	Variation of the obturator foramen and pubic arch of the female bony pelvis	Ridgeway, et al	Am J Obstet Gynecol 2008;198:546.e1-546.e4	
	Functional Results After Tape Removal for Chronic Pelvic Pain Following Tension-Free Vaginal Tape or Transobturator Tape	Rigaud, et al		
2012-01-01	Utero-vaginal suspension using a bilateral vaginal anterior sacrospinous fixation with mesh. Preliminary results	Rivaux, et al	Progres en urologie (2012) 22 , 1077-1083	BSCM07200024181
2004-09-30	Decompression and Transposition of the Pudendal Nerve in Pudendal Neuralgia: A Randomized Controlled Trial and Long-Term	Robert, et al	European Urology 47 (2005) 403–408	
2009-01-01	Patient expectations, subjective improvement and objective cure: is there a difference between the transobturator tape and the tension free vaginal tape procedure?	Robert, et al		BSCM04800001180
	Overactive Bladder: Diagnosis and	Robinson, Cardozo		
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2008-01-01	Urinary Stress Incontinence in Women	Rogers	N Engl J Med 2008;358:1029-	
2013-01-01	Current trends in surgical repair of pelvic organ prolapse	Rogo-Gupta L	Curr Opin Obstet Gynecol 25:395-398	
2013-01-01	Long-Term Symptom Improvement and Overall Satisfaction After Prolapse and Incontinence Graft Removal	Rogo-Gupta, et al	Female Pelvic Med Reconstr Surg 2013;19: 352Y355	
2010-04-01	Complications of Mesh-Augmented Pelvic Organ Prolapse and Incontinence Repairs: Case Series of 319 Procedures abstract	Rogo-Gupta, et al	Abstract	
2013-01-01	Pain Complications of Mesh Surgery	Rogo-Gupta, Raz	Complications of Female Incontinence and Pelvic	
2013-06-08	Mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair	Rogowski, et al	Int Urogynecol J (2013) 24:2087–2092	

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2008-00-00	Surgeons' experience and interaction effect in randomized controlled trials regarding new surgical procedures	Roman, et al	Am J Obstet Gynecol, 199(2), 108 e101-106	
2012-10-01	MULTI-CENTER RETROSPECTIVE CLINICAL EVALUATION OF THE LONG TERM OUTCOMES FOLLOWING PELVIC ORGAN PROLAPSE REPAIR USING PINNACLE PFR KIT (ANTERIOR	Rosenblatt, et al	Female Pelvic Medicine & Reconstructive Surgery, Volume 18, Number 8, Supplement 1	
	Evulation of Force Required to Replace Two Different Trocar-less Pelvic Floor Repair Kit Mesh Legs from the Sacrospinous Ligaments in a Cadaver Model	Rosenblatt, et al	ICS IUGA Abstract 682	
2007-12-01	Neurovascular anatomy of the sacrospinous ligament region in female cadavers: Implications in sacrospinous ligament fixation	Roshanravan, et al	Am J Obstet Gynecol 2007;197:660.e1-660.e6	
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2007-00-00	Management of persistent groin pain after transobturator slings	Roth TM	Int Urogynecol J (2007) 18:1371--1373	
2013-01-01	Controversies and consensus in female urology: a case based approach	Rovner, et al	AUANews	
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2013-01-01	Complications of Transvaginal Apical Repairs: Evaluation and management	Sajadi, Vasavada	Complications of Female Incontinence and Pelvic	
2011-04-01	One Year Outcomes on Vaginal Mesh With Sacrospinous Ligament Attachment Through the Anterior Approach	Salamon, et al	Female Fe/v/c Ivmedicine Sr Heconr(rac(ive Surgery ~ Volume 17, Number 2,	
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2009-01-01	RETROPUBIC TVT VS TRANSOBTURATOR OUTSIDE-IN TOT AND INSIDE-OUT TVT-O – ONE-YEAR RESULTS FROM OUR PROSPECTIVE RANDOMIZED STUDY	Scheiner, et al	ICS 2009	
	Effectiveness of Tension-Free Vaginal Tape Compared With Transobturator Tape in Women With Stress Urinary Incontinence and Intrinsic Sphincter Deficiency: A Randomized Controlled Trial	Schierlitz, et al	Obstet Gynecol 2008;112:1253-61	
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2012-04-01	Mesh complications in female pelvic floor reconstructive surgery and their management: A systematic review	Shah, Badlani	Indian J Urol. 2012 Apr-Jun; 28(2): 129–153	
2008-01-01	The age distribution, rates, and types of surgery for pelvic organ prolapse in the USA	Shah, et al	Int Urogynecol J (2008) 19:421–428	
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2013-01-01	Surgical Management of Lower Urinary Mesh Perforation after Mid-Urethral Polypropylene Mesh Sling: Mesh Excursion, Urinary Tract Reconstruction and Concomitant Pubovaginal Sling with Autologous Rectus Fascia	Shah, et al	Int Urogynecol J (2013) 24:2111–2117	

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	Transobturator mesh for cystocele repair: a short- to medium-term follow-up using	Shek, et al		
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2003-01-01	Vaginal Anatomy and Physiology	Siddique S	J Pelvic Med Surg	
	Vaginal Mesh Extrusion Associated with Use of Mentor Transobturator Sling	Siegel A		
2007-01-01	Degradation Studies of Some Polymeric Biomaterials: Polypropylene (PP) and Polyvinylidene Difluoride (PVDF)	Silva, et al.	MATERIALS SCIENCE FORUM 539-43: 573-76	
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2005-09-28	Comparative study of autologous pubovaginal sling and synthetic transobturator (TOT) SAFYRE sling in the treatment of stress urinary incontinence	Silva-Filho, et al	Arch Gynecol Obstet (2006) 273: 288–292	
2011-04-30	Vaginal prolapse repair using the Prolift kit: a registry of 100 successive cases	Simon, Debodinance	European Journal of Obstetrics & Gynecology and	
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2007-09-28	A randomized comparison of polypropylene mesh surgery with site-specific surgery in the treatment of cystocele	Sivaslioglu, et al	Int Urogynecol J (2008) 19:467–471	
2011-07-11	Mesh complications following prolapse surgery: management and outcome	Skala, et al	European Journal of Obstetrics & Gynecology and	
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	In vivo comparison of suburethral sling	Slack, et al		
2012-01-01	A standardized description of graft-containing meshes and recommended steps before the introduction of medical devices for prolapse surgery	Slack, et al	Int Urogynecol J (2012) 23 (Suppl 1):S15–S26	
2006-01-01	Long-term outcomes and review of complications in 75 patients with Boston Scientific Advantage Mesh in mid-urethral	Smith, Bresette		BSCM04800000034
2013-01-01	Pathologic Evaluation of Explanted Vaginal Mesh: Interdisciplinary Experience From a Referral Center	Smith, et al	Female Pelvic Med Reconstr Surg 2013;19: 238-241	
2011-01-01	Single-incision Midurethral tape (Ophira) vs. Transobturator tape (Obtryx): Prosepective comparative study at a median follow-up of 6 months	Smith, et al	IUGA Poster	

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2013-08-01	Comparison of single-incision mid-urethral tape (Ophira) and transobturator tap (Obtryx) suburethral sling procedures for female stress urinary incontinence	Smith, et al	Journal of Clinical Medicine and Research	
2011-07-25	Society of Gynecologic Surgeons (SGS) Executive Committee Statement Regarding the FDA Communication	Society of Gynecologic Surgeons (SGS) Executive Committee		
2012-01-01	One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse	Sokol, et al	Am J Obstet Gynecol 2012;206:86.e1-9	
	Tension free monofilament macropore polypropylene mesh (Gynemesh PS) in female genital prolapse repair	Sola, et al		
2009-01-01	The 7-year outcome of the tension-free vaginal tape procedure for treating female stress urinary incontinence	Song, et al	BJU International	
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2011-10-06	Traditional native tissue versus mesh augmented pelvic organ prolapse repairs: providing an accurate interpretation of	Stanford, et al	Int Urogynecol J (2012) 23:19-28	
	A Comprehensive Review of Suburethral Sling Procedure Complications	Stanford, Paraiso		
1999-01-14	Nerve irritation after laparoscopic hernia	Stark, et al	Surg Endosc (1999) 13:	
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2010-01-01	Midurethral Sling Procedures for Stress Urinary Incontinence in Women Over 80	Stav, et al	Neurourology and Urodynamics 29:1262-1266	
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2010-04-01	One-year Anatomic And Quality Of Life Outcomes Following The Anterior Pinnacle Lift Kit Procedure For The Treatment Of Pelvic	Steinberg, et al	Female Pelvic Medicine & Reconstructive Surgery; Vol. 16, #2 Suppl	BSCM06100141079
	One-Year Anatomic and Quality of Life Outcomes Following the Anterior Pinnacle Lift Kit Procedure for the Treatment of Pelvic	Steinberg, et al	Oral Poster 14	
2009-01-01	Vaginal Reconstructive Surgery Using Pinnacle Mesh Kit vs Open Abdominal vs Laparoscopic Sacrocolpopexy - Comparison of Outcomes	Sternchuss, et al	Journal of Minimally Invasive Gynecology 16 (2009) S44	
2012-07-01	Post-Implantation Alterations of Polypropylene in the Human	Sternschuss, et al	J Urol 188:27-32	
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2006-07-06	The in vitro effect of hydrogen peroxide on vaginal microbial communities	Strus, et al	FEMS Immunol Med Microbiol 48 (2006)	
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2001-10-01	Cost of Pelvic Organ Prolapse Surgery in the United States	Subak, et al	Obstet Gynecol 2001;98:646 –51	
	Total Pelvic Mesh Repair	Sullivan, et al		
2011-00-00	Is transobturator suburethral sling effective for treating female urodynamic stress incontinence with low maximal urethral	Sun, Tsai	Taiwanese Journal of Obstetrics & Gynecology 50 (2011) 20-24	

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	Judging clinical research questions: what criteria are used?	Sutherland, et al		
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2002-07-01	Polypropylene mesh tape for Stress Urinary Incontinence	Sweat, et al	J Urol Vol. 168, 144--146	
2007-03-21	"First do no harm" and the emerging story of the vaginal reconstructive mesh implant	Swift S	Int Urogynecol J (2007) 18:983-984	
2004-10-14	Pelvic Organ Support Study: The distribution , clinical definition, and epidemiologic condition of pelvic organ support defects	Swift, et al	American Journal of Obstetrics and Gynecology (2005) 192, 795-806	
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1997-01-01	Transvaginal Repair of vault prolapse: A	Sze, Karram	Obstet Gynecol 1997;89:466-	
2011-01-01	Fish Bone Chemistry and Ultrastructure: Implications for Taphonomy and Stable Isotope Analysis	Szpak P	Journal of Archaeological Science (2011), doi: 10.1016/j.jas.2011.07.022	
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2008-01-01	TVT and TOT - a comparison between these two techniques based on our clinical	Tamai, et al	Urologia 75(4):232-236	
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	Repair of Groin Hernia With Synthetic Mesh: Meta-Analysis of Randomized Controlled	The EU Hernia Trialists Collaboration		
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2010-01-01	ONE YEAR RESULTS OF A PROSPECTIVE RANDOMIZED TRIAL COMPARING THE ORIGINAL INSIDE-OUT TRANSOBTURATOR (TVT-O™) PROCEDURE AND A MODIFIED VERSION USING A SHORTENED TAPE AND REDUCED DISSECTION FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE	Thomas, et al	Int Urogynecol J (2010) 21 (Suppl 1):S1—S428	
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2009-02-04	Perineal approach to vascular anatomy during transobturator cystocele repair	Touboul, et al	BJOG 2009;116:708-712	
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2014-01-01	Overview of transvaginal placement of reconstructive materials (surgical mesh or biografts) for treatment of pelvic organ prolapse or stress urinary incontinence	Trabuco, Gebhart	UpToDate	
2011-08-30	Safety and Effectiveness of Transvaginal Surgical Mesh Used for Repair of Pelvic Organ	Transvaginal mesh Industry Working Group, et al		
2014-01-01	Characteristics and temporal trends in patient registries: focus on the life sciences industry, 1981–2012	Travers, et al	Pharmacoepidemiology and Drug Safety	
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2007-01-01	Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or	Tunn, et al	Ultrasound Obstet Gynecol 2007; 29: 449–452	
	The aetiology of bacterial vaginosis	Turovskiy, et al		
	Complications of Synthetic Mid-Urethral	Twiss, Raz		
2014-01-01	IN-DEPTH NANO-INVESTIGATION OF VAGINAL MESH AND TAPE FIBER EXPLANTS IN WOMEN	Tzartzeva, et al	Abstract	
1996-01-01	An ambulatory surgical procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence	Ulmsten, et al	Int Urogynecol J (1996) 7:81—86	
1999-01-01	A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence	Ulmsten, et al	British Journal of Obstetrics and Gynaecology April 1999, Vol 106, pp. 345-	
1998-01-01	A Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence	Ulmsten, et al	Int Urogynecol J (1998) 9:210—213	
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2008-01-01	The Trial of Mid-urethral slings [TOMUS]: Design and Methodology	Urinary Incontinence Treatment Network	J App Res 8,1:1-13	
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2008-01-01	TORP - Comparing the efficacy, execution and early complications of TVT and TVT-O	Valentim-Lourenco, et al	Int Urogynecol J (2008) 19 (Suppl 1):S1–S166	

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	Mesh Complications-A Review of the Basic Categories	Vardy M	Urogyn Update Volume 28, Number 1	
2007-06-16	All oral presentations made at the 32nd Annual IUGA Meeting	Various		
2008-08-01	3-D Ultrasound Characterization of Mid-Urethral Slings: A Comparison of Three Different Sling Types	Vassallo, et al	journal of Pelvic Medicine & Surgery Volume 14, Number 4	
2010-01-05	Transvaginal mesh repair of anterior and posterior vaginal wall prolapse: a clinical and ultrasonographic study	Velemir, et al	Ultrasound Obstet Gynecol 2010; 35: 474–480	
	Nerve injury: an exceptional cause of pain after TVT	Vervest, et al	Int Urogynecol J (2006) 17: 665—667	
	TRANSOBTURATOR TAPE (TOT), INSIDE-OUT OR OUTSIDE-IN APPROACHES: DOES IT	Vervest, et al		
	Midurethral sling incision: indications and outcomes	Viereck, et al		
2003-12-10	The use of pessaries in vaginal prolapse	Vierhout M	European Journal of Obstetrics & Gynecology and	
2008-01-01	Robotic Gynecologic Surgery	Visco, Advincula	Obstet Gynecol	
2000-06-21	Vaginal mesh erosion after abdominal sacral colpopexy	Visco, et al	Am J Obstet Gynecol 2001;184:297-302	
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2003-02-01	Surgical Intervention for Complications for the Tension-free Vaginal Tape Procedure	Volkmer, et al	J Urol Vol. 169, 570-574	
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